

PCT

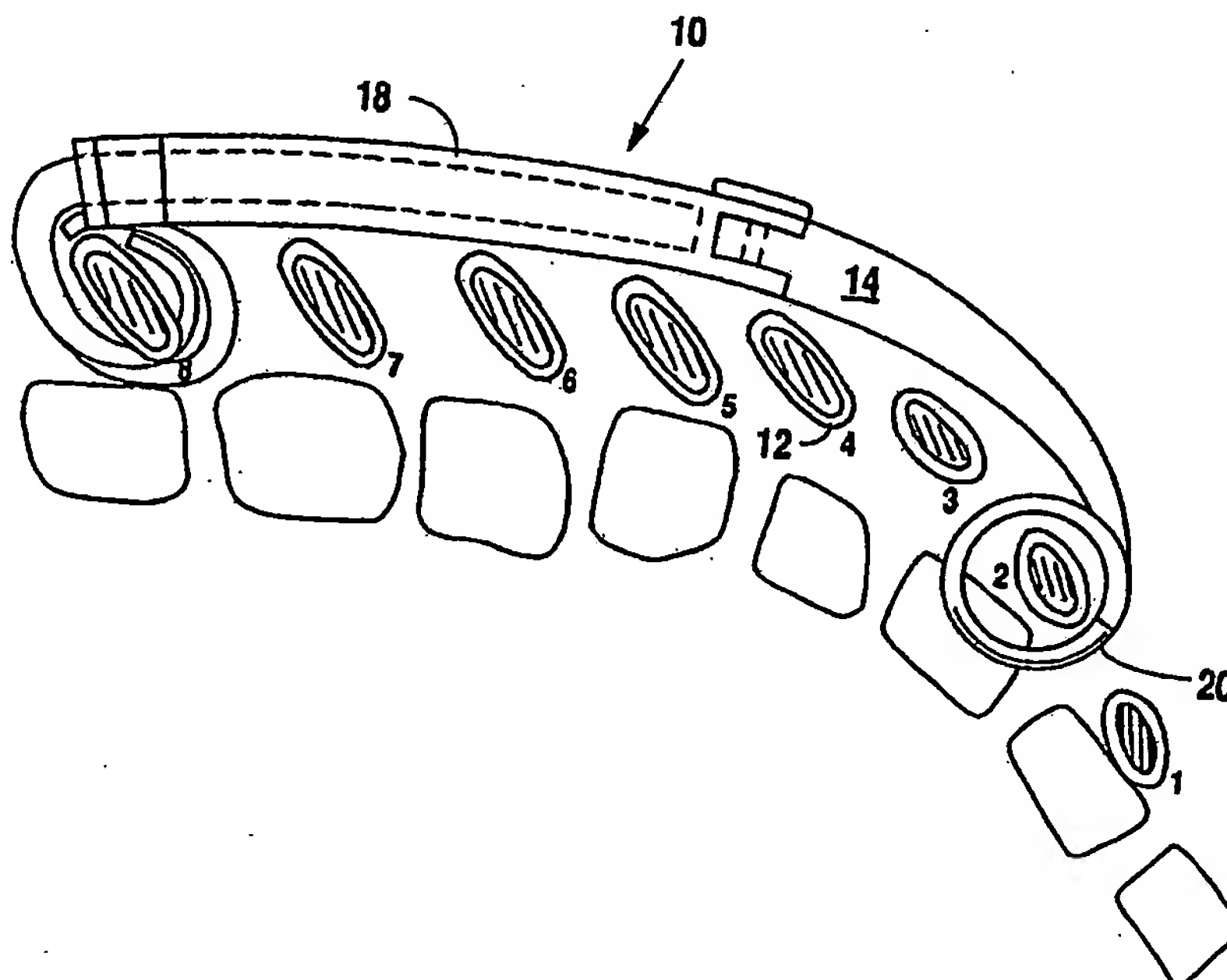
WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61F 2/28, A61B 17/56		A1	(11) International Publication Number: WO 93/22989 (43) International Publication Date: 25 November 1993 (25.11.93)
(21) International Application Number: PCT/US93/04720 (22) International Filing Date: 18 May 1993 (18.05.93) (30) Priority data: 07/885,346 19 May 1992 (19.05.92) US (60) Parent Application or Grant (63) Related by Continuation US Filed on 07/885,346 (CIP) 19 May 1992 (19.05.92) (71)(72) Applicant and Inventor: CAMPBELL, Robert, M. Jr. [US/US]; 415 Stone Wood, San Antonio, TX 78216 (US).		(74) Agent: HENRY, David, G.; 515 Congress Ave., Suite 2300, Austin, TX 78201 (US). (81) Designated States: AU, BR, CA, FI, JP, KP, KR, NO, NZ, PL, RO, RU, SD, SK, UA, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.	

(54) Title: TREATMENT OF THORACIC DEFORMITIES SUCH AS SCOLIOSIS



(57) Abstract

Applicant's invention includes an apparatus (10, 110, 210, 310) and associated method for treating or managing spinal deformities. For purely thoracic scoliosis, the apparatus is attachable to either first and second ribs (12) (for treatment of thoracic scoliosis) and a distal thoracic rib, or to a distal thoracic rib and an attachment point on the sacrum (212) for treatment of lumbar scoliosis.

BEST AVAILABLE COPY

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	MR	Mauritania
AU	Australia	GA	Gabon	MW	Malawi
BB	Barbados	GB	United Kingdom	NL	Netherlands
BE	Belgium	GN	Guinea	NO	Norway
BF	Burkina Faso	GR	Greece	NZ	New Zealand
BG	Bulgaria	HU	Hungary	PL	Poland
BJ	Benin	IE	Ireland	PT	Portugal
BR	Brazil	IT	Italy	RO	Romania
CA	Canada	JP	Japan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SK	Slovak Republic
CI	Côte d'Ivoire	LI	Liechtenstein	SN	Senegal
CM	Cameroon	LK	Sri Lanka	SU	Soviet Union
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	MC	Monaco	TG	Togo
DE	Germany	MG	Madagascar	UA	Ukraine
DK	Denmark	ML	Mali	US	United States of America
ES	Spain	MN	Mongolia	VN	Viet Nam
FI	Finland				

"TREATMENT OF THORACIC DEFORMITIES SUCH AS SCOLIOSIS"

Citation to Prior U.S. Application(s)

This is a continuation-in-part application with
5 respect to U.S. Application Serial No. 07/885,346 filed
May 19, 1992 (19.05.92) which was a continuation-in-part
of Application No. PCT/US90/0218 filed, as a PCT applica-
tion on April 13, 1990 (13.04.90) and which entered the
national stage in the United States on October 21, 1991
10 (21.10.91). U.S. Application Serial No. PCT/US90/0218 was
a continuation-in-part of U.S. Application No. 07/338,227
which issued on March 3, 1992 (03.03.92) as U.S. Patent
No. 5,092,889. Sole inventorship with respect to this
Application and each of the foregoing lies with the
15 present Applicant.

Field of the Invention

Applicant's invention relates to diseases and
symptoms evidenced as deformities in the human skeletal
systems.

20 Background of the Invention

The human spine is a system which consists of a
succession of vertebral bodies which, in its normal state,
extends within and defines a single sagittal plane.
Ideally, there should be substantially no deviation in the
25 frontal plane (perpendicular to the sagittal plane from a
straight line. Within the sagittal plane, a certain
degree of lumbar lordosis and thoracic kyphosis is normal
and desirable. An excess degree of lumbar curvature is
known as hyperlordosis, while an abnormally flat lumbar
30 succession of vertebral bodies is known as hypolordosis.
In like manner, hyperkyphosis (most commonly seen in
Scheuermann's disease) is that condition evidenced by a
greater-than-normal degree of curvature in the thoracic
spine which gives a hump-back type appearance.

Scoliosis may be defined as lateral deviation and rotation of a series of vertebrae from the midline anatomic position of the normal spine axis. The deformity occurs in three planes - frontal, sagittal and transverse.

5 Scoliosis, in its more severe embodiments, is a debilitating, if not deadly disease. With the progression of the curve, structural changes occur in the vertebrae and in the formation and contour of the rib cage. This, in turn, often threatens respiratory function and

10 capacity. The curvature of the spine itself can pose danger to the spinal cord. Still further, the interrelationships between other thoracic and abdominal organs are changes and the normal function thereof is imperilled. Fully 80% of all scoliosis cases are

15 idiopathic, i.e. the cause is cause unknown.

There is no present "cure" for scoliosis as such, but treatments of the symptoms have been known for some time - treatments with often-times questionable effectiveness, inherent intra-surgical danger to the patient, frequent

20 patient discomfort and/or substantial inconvenience, and substantial likelihood of post-operative complication.

Non-surgical control of scoliosis (as distinguished from correction) is available. Such non-surgical treatments include physical therapy, biofeedback,

25 electrical stimulation and orthosis (the Sayre cast, the Hibbs and Risser casts, the Milwaukee brace, the Boston brace and the Wilmington brace, for example). Reportedly, however, these non-surgical methods can collectively boast, at most, only a 70% success rate in arresting

30 further progression of scoliosis in cases of proven curve progression in growing (relatively immature) spines. Many of these non-surgical methods are contraindicated in cases involving curvatures greater than a specific range (usually about 40 degrees), certain patients with physical

infirmities in addition to the scoliosis, patients with certain remaining growth potential, and/or with patients who cannot be reasonably expected to rigorously follow a prescribed therapeutic regimen or to emotionally tolerate the limitations and appearances of the various braces.

Surgical intervention in the correction of scoliotic curvature presently involves spinal instrumentation and spinal fusion first pioneered by Hibbs, et al.¹ One without the other is generally viewed as ineffective under current convention. The over-all objective of the surgical intervention is to correct the scoliosis as much as is possible, and to restore compensation of the spine with a symmetrical trunk and with head, neck and shoulders centered over the pelvis; and to stabilize the spine and prevent curve progression. The objective of the spinal instrumentation portion of surgical treatment of scoliosis is to immediately correct curvature to the degree possible and to immobilize the spine in the corrected orientation until a solid fusion has taken place.

Problems abound with currently available spinal instrumentation. Some instrumentation occupies space needed for the bone graft placed over the posterior spine. Also, the attachment means used for spinal instrumentation inherently risks intra-operative spinal cord damage with the potential for irreversible paralysis. Still further, many spinal instrumentation systems are prone to disengagement because their attachment schemes involve screws (prone to disengage from atrophic vertebrae) or hooks which only partially encircle vertebral body projections (prone to dislodging during movement).

¹ Hibbs, R.A., Risser, J.C. and Ferguson, A.B.: "Scoliosis treated by the fusion operation." J. Bone Joint Surg., 6:3, 1924.

"Harrington Instrumentation"^{2,3} is the posterior spinal instrumentation by which all current systems are compared. In this system, bone-purchasing hooks are attached to posterior elements of the spine -- facets, 5 laminae, and transverse processes. Through these hooks, distraction forces are applied to the concave side of the spinal curve by the ratchet principle, and compression forces are applied on the convex side of the thoracic curve at the base of the transverse processes and adjusted 10 by the threadnut principle.

Despite its prominence, the Harrington system has drawbacks: (1) failure of derotation of the spine as the distraction force straightens the lateral curvature; as a result the rib hump is not corrected; (2) the distraction 15 forces of the Harrington instrumentation flatten the spine with the result that the normal lumbar lordosis is obliterated thereby producing a marked deformity; (3) Harrington instrumentation does not provide enough stability to the spine and, therefore, postoperative 20 immobilization is required in the form of a cast or spinal orthosis; (4) the bulky nature of the Harrington instrumentation is such that it protrudes well beyond the normal dorsal contour thereby "tenting up" the overlying skin and causing breakdown problems; and (5) Harrington 25 instrumentation does not accommodate growth in cases of implantation in children; and (6) direct exposure of the spinal components to any spinal instrumentation often promotes inadvertent spinal fusion.

30 ² Harrington, P.R.: Treatment of Scoliosis. Correction and internal fixation by spine instrumentation. J. Bone Joint Surg., 44-A:591, 1962.

35 ³ Harrington, P.R.: Surgical instrumentation for management of scoliosis. J. Bone Joint Surg., 42-A:1448, 196.

A relatively new system (the Cotrel-Dubousset [C-D] Instrumentation⁴) is a segmental spinal instrumentation that addresses many of the Harrington system's shortfalls. Nevertheless, C-D instrumentation exhibits its own 5 shortcomings, the principle one being that it is complex and cumbersome, with too many "moving parts". Also, implantation is extremely complex and requires the skills and experience possessed by few practitioners. It obscures the posterior spine; limiting the amount of bone 10 graft surface for biologic fusion.

One current form of anterior segmental instrumentation for treatment of scoliosis is the Zielke instrumentation⁵. This system, however, obviously involves accessing the anterior surfaces of the spinal column to 15 attach instrumentation. This, in turn, carries a significant risk of neural and vascular injury with the accompanying risk of partial or total paralysis.

The history of scoliosis and its treatment yields as its less a seeming paradox: it is dangerous (and often 20 ineffective) to treat the spine in addressing spine anomalies. This paradox has heretofore remained unsolved for two primary reasons: (1) the causation and mechanisms of scoliosis are not understood and, therefore, cannot be addressed in a preventative or even curative manner; and 25 (2) direct management of an affected system (in this case the spine) is the traditional approach common to virtually all orthopedic procedures, a predisposition which yields a myopic view of the possible remedies as evidenced by the

30 ⁴ Cotrel, Y. and Dubousset, J.: New Segmental posterior instrumentation of the spine. Orthop. Trans., 9:118, 1985.

⁵ Zielke, K. and Pellin, B.: Neue Instrumente and Implantate zur Erganzung des Harrintson Systems. Z Orthop. Chir, 114: 534, 1976.

spinal instrumentation of the prior art.

Summary of the Invention

It is an object of the present invention to provide
5 novel and non-obvious instrumentation for treatment and management of scoliosis.

It is another object of the present invention to provide a novel method for the treatment and management of scoliosis.

10 It is another object of the present invention to provide instrumentation of the treatment and management of scoliosis which instrumentation avoids direct affixation to vertebrae.

It is another object of the present invention to
15 provide a method for the treatment and management of scoliosis which method does not involve direct affixation of instrumentation to spinal components.

It is another object of the present invention to provide novel instrumentation for the treatment and
20 management of scoliosis the implantation of which instrumentation involves less risk of injury to the recipient than does presently available instrumentation.

It is another object of the present invention to provide novel method for the treatment and management of
25 scoliosis which method involves less risk of injury to the recipient of treatment therethrough than does presently available methods of treatment and management.

It is another object of the present invention to provide novel instrumentation for the treatment and
30 management of scoliosis which instrumentation is less prone to produce deleterious, post-operative side effects than do presently available instrumentation systems.

It is another object of the present invention to provide novel instrumentation for the treatment and

management of scoliosis which instrumentation, when implanted, lies lateral to the spinal column and does not, therefore, obstruct access to the vertebrae to be fused as part of scoliosis treatment.

- 5 It is another object of the present invention to provide novel instrumentation for the treatment and management of scoliosis which instrumentation is adjustable in such a manner as to accommodate growth of a child recipient.
- 10 It is another object of the present invention to provide novel instrumentation for the treatment and management of scoliosis which instrumentation is adjustable in such a manner as to allow dynamic treatment over time.
- 15 It is another object of the present invention to provide novel instrumentation for the treatment and management of scoliosis which instrumentation is adjustable for accommodation of growth or for allowing dynamic treatment and which adjustment is achievable on an
- 20 out-patient basis because of novel and non-obvious adjustment means.

It is another object of the present invention to provide instrumentation for the treatment and management of scoliosis which instrumentation effectively corrects

25 the abnormal curvature(s) thereof, accommodates normal degrees of kyphosis and lordosis, and does not require direct involvement of the vertebrae.

It is another object of the present invention to provide novel instrumentation for the treatment and

30 management of scoliosis the implantation of which instrumentation, because of simplified rib attachment means, lacks any substantial requirement of training or prior experience.

In satisfaction of these and related objectives,

Applicant's present invention provides, instrumentation for treatment and management of scoliosis through manipulation, not of the spine, but of the adjacent ribs.

The instrumentation comprises an expandable shaft member (hereinafter referred to as a "thoracodorsal distractor") which is attachable at a first of its two ends to a proximal thoracic rib immediately adjacent to the spine and at the second end to a distal rib adjacent to the spine. The thoracodorsal expander is contoured for initially conforming to a merely slightly corrected scoliotic deformity and thereafter, through successive adjustments, for defining and imposing upon the patient's dorsum a substantially normal dorsal contour from the thoracic to the sacral segments thereof.

More specifically, the shaft defines a contour in the sagittal plane which exhibits a complex curve. Consistent with the curvature defined by the trough or "posterior gutter" which is collectively defined by the ribs' arcual* deviation lateral to the spinal column and medial to posterior angle of each rib, the proximal portion of the thoracodorsal distractor which is to overlies the proximal thoracic ribs defines a curvature in the sagittal plane of a smaller radius than that of the remaining extent (the distal portion) of the distractor which is to overlies the more distal thoracic and the lumbar regions of the dorsum.

The just-referenced proximal portion of the shaft of Applicant's instrumentation is of a fixed length and contour, while the distal portion is a telescopically adjustable unit which expands and contracts in length within a single arc of curvature (of substantially larger radius than that of the proximal portion of the shaft).

One mode of practice for Applicant's methods claimed herein involves placement of Applicant's instrumentation on either side of the scoliotic spine. One shaft is to

act as a distractor (on the concave side of the curvature), the other as a means of compression (on the convex side). In the former instance, the shaft is implanted in a contracted or shortened state. The shaft
5 will be sized to exert a distractive force on the sacrum and the proximal attachment rib thereby tending to straighten the intervening length of the spinal column. The shaft will be expanded in length through successive post-implantation adjustments as the scoliotic curvature
10 is gradually corrected.

On the convex side of the scoliotic curvature, the opposite is true -- the shaft is implanted in a relatively expanded state and exerts a suitable initial compressive force as between the proximal attachment rib and the
15 distal rib. This directly compliments and supplements the corrective action of the shaft unit on the concave side of the curvature. As the dynamic treatment progresses, the convex side shaft is shortened through successive adjustments.

20 The shafts further serve as a platforms from which metallic slings are suspended to encircle and draw toward the shaft selected, mis-oriented ribs which lie thereunder. In this manner, the instrumentation serves to derotate vertebrae to which the ribs manipulated in this
25 manner are attached.

Applicant's thoracodorsal distractors present drastic improvements over the scoliotic treatment instrumentation and methods of the prior art. By attaching to the ribs adjacent the spine, rather than to the spine itself,
30 substantial risk of irreversible neural injury is eliminated. The positioning of the implanted distractors allows ready access to the spine for spinal fusion procedures. In patients, because of skeletal immaturity, use of the distractor reduces the chance of inadvertent

spinal fusion as a result of direct exposure of the spine to the instrumentation. Furthermore, the expandability of the thoracodorsal expanders allows dynamic treatment scoliosis as well as the accommodation of growth when
5 implanted in children. Further still, the size and contour of the distractors also reduce the likelihood of skin necrosis which attends use of the bulky, protruding instrumentation of the prior art.

Such benefits would be inherent in the thoracodorsal
10 distractors regardless of the attachment means (so long as its is stable as to the proximal rib and distal rib). The device also can extend from a distal rib to the sacrum for the purpose of treating lumbar scoliosis. Nevertheless, Applicant has derived rib and sacral attachment means
15 which are both virtually infallible (subject to bone integrity) and relatively easy to operate. These improvements (to be described in detail in the detailed description of the preferred embodiment) represent a departure from and an improvement over Applicant's prior
20 inventions, the embodiments of which attach to ribs and require considerably advanced skill and experience to safely and effectively implant.

Applicant also provides a length adjustment system for his thoracodorsal distractors which is, after
25 implantation, very simply operable through very small puncture wound-like incisions.

Brief Description of the Drawings

Fig. 1 is an elevational side view of a thoracodorsal
30 distractor of Applicant's invention (with simple rod-type rib carriages) in a contracted, or shortened configuration.

Fig. 2 is the thoracodorsal distractor of Fig. 1 shown in top plan view.

Fig. 3 is a side elevational view of the distractor of Figs. 1 and 2 shown in a telescopically expanded configuration.

Fig. 4 is a cross sectional view of the distractor sleeve at line B - B of Fig. 3.

Fig. 5 is a cross sectional view of the distractor shaft along line A - A of Fig. 3.

Fig. 6 is a perspective anatomical view of two thoracodorsal expanders of Applicant's invention shown implanted on either side of a patient's spinal column. The left distractor is shown attached at its proximal end to a thoracic rib and at its distal end to the sacrum. Upper portion of the depiction of the right distractor is shown as a substantially like embodiment to the left distractor, with the lower portion mimicking a conventional segmental spinal hook system attachable directly to the spine by hooks (such as a Harrington rod system). Metallic slings are shown as connecting intermediate ribs to the distractors.

Fig. 7 is an elevational, partially sagittally cross sectional view of the proximal portion of a thoracodorsal distractor of Applicant's invention. This view depicts the increased curvature of the proximal portion of the distractor so as to accommodate the more curved contour of the more proximal thoracic ribs at the distractor's line of attachment thereto.

Fig. 8 is a side elevational view of a segment of a thoracodorsal distractor as connected to a rib (shown in cross section) by way of a metallic sling.

Fig. 9 is a side elevational view of the auto-lock rib carriage of Applicant's preferred embodiment.

Fig. 10 is the auto-lock rib carriage of Fig. 9 with the upper carriage in the closed position.

Fig. 11 is a elevational front view of the auto-lock

rib carriage of Fig. 9 with the over carriage in the open position.

Fig. 12 is a elevational front view of the auto-lock rib carriage of Fig. 9 with the over carriage in the closed position.

Fig. 13 is a collection of three view of the saddle lock for use with the auto-lock rib carriage of Fig. 9.

Fig. 14 is a pair of views of the carriage shaft lock for use with the auto-lock rib carriage of Fig. 9.

10 Fig. 15 is a perspective view of a straight rib sleeve (for use in treating lumbar spine anomalies) attached by a saddle bracket to the patient's sacrum.

Fig. 16 is an elevational view (partial cross-sectional) of the pestle joint of the saddle bracket of 15 Fig. 15.

Fig. 17 is a bottom plan view of a portion of a thoracodorsal distractor having Applicant's improved expansion system.

Fig. 18 is a top plan, partial cut-away view of the 20 portion of the thoracodorsal distractor of Fig. 17.

Fig. 19 is an enlarged portion of Fig. 17 with the distractor shaft removed for visibility of the rack portion of Applicant's improved expansion system.

Fig. 20 is a cross-sectional view (perpendicular to 25 the long axis of the distractor) of a portion of Applicant's improved expansion system with the geared probe shown close to operative position for operation of the system.

Fig. 21 is a side elevational view of the probe used 30 in Applicant's improved expansion system for the thoracodorsal distractor.

Fig. 22 is an end elevational view of the tip of the probe of Fig. 21 showing the gear and pin affixed at the distal end thereof.

Fig. 23 is a cross-sectional view (perpendicular to the long axis of the distractor) of a portion of Applicant's improved expansion system.

Fig. 24 is a side elevational view of a portion of Applicant's improved expansion system showing operation and position of the ratchet mechanism portion of such system.

Fig. 25 is a bottom plan view of the ratchet mechanism component of Applicant's improved expansion system for his thoracodorsal distractor.

Fig. 26 is an end elevational view of the ratchet mechanism of Fig. 25.

Fig. 27 is an elevational, partially cross-sectional view of the micro access distraction lock component of Applicant's improved expansion system for his thoracodorsal distractor.

Fig. 28 is an exploded, side elevational view of the locking disk and hex screwdriver components of the micro access distraction lock component of Applicant's improved expansion system for his thoracodorsal distractor.

Fig. 29 is a bottom plan view of the threaded cap disk of the locking disk of Fig. 28.

Fig. 30 is a bottom plan view of the threaded cap disk of the locking disk of Fig. 28.

25

Detailed Description of the Preferred Embodiment

Referring to FIG. 1, a first embodiment of the device of Applicant's invention (hereinafter usually referred to as the "thoracodorsal distractor") is identified generally by the reference numeral (10). This embodiment is the simplest one and is designed, by virtue of its attachment means (to be identified later) to be attached to proximal thoracic and distal lumbar natural ribs. Alternative embodiments with different attachment means at the distal

end of the distractor will be discussed later herein.

The thoracodorsal distractor (10) is designed to be adjusted in length subsequent to implantation. The primary purpose of the adjustability being to accommodate growth of a child in whom the thoracodorsal distractor (10) is implanted or to allow for dynamic treatment scoliosis and other spinal anomalies (to be discussed later). The adjustability is also a benefit in using a single sized thoracodorsal distractor (10) for applications requiring varying distractor lengths. This permits use of a single sized distractor (10) in a single patient in different positions or in different patients with varying physiological dimensions. Both of these scenarios have obvious financial benefits to the patient(s) when compared with having a number of custom fabricated prostheses made for very specific, limited applications.

Referring to FIGS. 1, 2, and 3, the thoracodorsal distractor (10) comprises three principal components: a proximal distractor sleeve carriage attachment (14), a distractor shaft/distal distractor shaft carriage attachment (16), and a distractor sleeve (18). The distractor shaft/distal distractor shaft carriage attachment (16) is a single object of unitary construction, but for discussion purposes may be divided between the distractor shaft (16a) and the distal distractor shaft carriage attachment (16b).

Unless otherwise specified, all components of the thoracodorsal distractor (10), except the distractor sleeve (18) which is made of Titanium Alloy 64, are manufactured of Commercially Pure (CP) Titanium. The use of titanium is dictated by the strength and flexibility requirements for the components of the thoracodorsal distractor (10) in light of the dimensions of such compo-

nents. Other materials, such as surgical grade stainless steel, may be used in constructing the thoracodorsal distractor (10), but at the expense of the optimum balance of benefits derived from titanium. Another benefit arising from the use of titanium is derived from the fact that it is not a ferromagnetic metal. As such, titanium is compatible with magnetic resonance imaging (M.R.I.) scanning, a much preferable diagnostic procedure, particularly with patients who would normally be considered as recipients of Applicant's thoracodorsal distractor (10).

The rods (20) of the carriage attachments (14) and (16b) serve as the attachment means for anchoring the thoracodorsal distractor (10) to natural ribs (12) and will be discussed in detail hereinafter.

Referring again to FIGS. 1, 2, 3 and 4, the distractor sleeve (18) may be described as an elongate, semi-oval partial conduit with a lengthwise oriented channel (22) interrupting the lower surface of the distractor sleeve (18). The presence of the channel (22) is in response to manufacturing cost limitations. It should be understood that a suitable alternative sleeve which lacks the channel (22) entirely (not shown in the drawings) would be acceptable for the purposes stated herein, but would be available, if at all, at a considerably higher price because of difficulties in manufacturing such a sleeve. For that reason, the depicted distractor sleeve (18) would be considered a preferred embodiment.

Referring to FIGS. 1, 2, 3 and 5, the distractor shaft (16a) is of solid construction and has a lengthwise oriented ridge (not visible in the drawings). The ridge is designed to mechanically interface with the channel (22) when the distractor shaft (16a) is telescopically received within interior lumen (24) of the distractor

sleeve (18) as it is designed to do. While the presence of the channel does tend to weaken the distractor sleeve (18) in resisting axial rotation relative to the distractor shaft (16a), or vice versa, when a torque is applied to either, the restraining action of the ridge's interface with the channel (22) compensates completely for any such tendency. Prior to incorporating the ridge into the distractor shaft (16a) design, experimentation revealed a marked tendency toward such rotation particularly when the thoracodorsal distractor (10) was extended to near its maximum extent.

The distractor shaft (16a) and the distractor sleeve (18) are formed whereby they jointly define a single arc having a constant radius of curvature in a single plane regardless of the degree the distractor shaft (16a) is received within the distractor sleeve (18). The distractor sleeve's (18) and distractor shaft's (16a) radius of curvature may be adjusted in the manufacturing process according to the expressed preference of the responsible surgeon, as dictated by the physiology of the intended recipient.

Referring principally to Figures 1 and 7, the proximal distractor sleeve carriage attachment (14) projects through the same plane as the distractor sleeve (18) and distractor shaft/distal distractor shaft carriage attachment (16) and is also arcual in configuration. However, the proximal sleeve carriage attachment (14) exhibits a curvature of smaller radius than that of the distractor sleeve (18) and distractor shaft/distal distractor shaft carriage attachment (16).

This is, as explained in the Summary of the Invention portion of this Application, to conform to the contour defined by portions of the more proximal, thoracic natural ribs (12) over which the thoracodorsal distractor (10)

extends once implanted (as in Figure 7). Both the proximal and distal portions of the thoracodorsal distractor are intended, in practicing the preferred mode of Applicant's methods for treating and managing scoliosis, to extend along the trough or "posterior gutter" collectively defined by the ribs on either side of and immediately adjacent to the spine (see FIG. 6).

By way of example only, Applicant has determined for one patient, a juvenile (at the time of this Application, not yet having received a thoracodorsal distractor) that the appropriate radius of curvature for the proximal distractor sleeve carriage attachment (14) is approximately 13.5 cm while that of the distractor shaft/distal distractor shaft carriage attachment (16) is approximately 40 cm.

Referring principally to FIGS. 1 and 3, the effective length of the thoracodorsal distractor (10) is determined by the length of the distractor sleeve (18) and the degree to which the distractor shaft (16a) is telescopically received within the distractor sleeve (18). The fixed length of the proximal distractor sleeve carriage attachment (14) is, of course, also partially determinative.

The variable spatial separation of the natural ribs 12 to which the implanted thoracodorsal distractor is attached is but one advantage of Applicant's design. It is important to note that as the distractor 10 is lengthened (as in the case where the distractor 10 is implanted on the concave side of a scoliotic curve wherein it is used to distract natural ribs 12 on either side of the curve and to thereby force the spinal column into a more straight orientation), its medial portions move posteriorly relative to the patient's central anatomical axis. This is a function of the arc in which the distal

portions of the distractor, as formed by the distractor sleeve (18) and the distractor shaft (16a), extend as they telescopically expand. Consequently, when natural ribs are tethered to the distractor (10) (as in Figure 6), they are drawn outward so as to more properly align them and to derotate the vertebrae to which these ribs (12) are attached. The combination of the distraction of the marginal attachment ribs (12) and the derotation of the spine as just described provides a highly effective treatment modality for the deviations in all planes associated with scoliosis.

To secure the relative positions of the distractor shaft (16a) and the distractor sleeve (18) once a desired length is attained, the distractor shaft (16a) has a plurality of evenly spaced holes (26) passing there-through. The distractor sleeve (18) of one embodiment has two holes (28) spaced complementarily to the holes (26) in the distractor shaft (16a). The holes (28) in the distractor sleeve (18) are situated on the outer face of the distractor sleeve (18). The proximal distractor sleeve carriage attachment (14) also has one hole (30) passing through its sleeve engaging projection (14a).

The holes (26), (28), and (30) are oriented whereby a linear object may concurrently extend through one of the two holes (28) in the distractor sleeve (18) and one of holes (26) in the distractor shaft (16a) when the distractor shaft (16a) is telescopically received within one end of the distractor sleeve (18). Likewise, a second linear object may extend through the other hole (28) in the distractor sleeve (18) and through hole (30) in the proximal distractor sleeve carriage attachment (14) when the sleeve projection (14a) is telescopically received and properly positioned within the other end of the distractor sleeve (18).

Referring principally to FIGS. 1 and 3, once the distractor shaft (16a) and the distractor sleeve (18) are properly, relatively positioned, they are secured using a distraction lock (32). One embodiment of the distraction lock (32) includes a pin (not separately identified in the drawings) long enough to extend through either holes (28) and (26) or through holes (28) and (30) when in position on the assembled thoracodorsal distractor (10), but not long enough to extend beyond the termini of the gripper flanges of the locks (32). The tip of the distraction lock's (32) pin as well as the termini of its gripper flanges are rounded. The limit on the length of the pin (34) and the just-referenced rounding are in satisfaction of safety concerns. Sharp edges and slender protrusions are to be avoided in anticipation of the distraction lock (32) possibly becoming dislodged after implantation and have been so avoided in Applicant's preferred embodiment of the distraction lock.

Referring principally to FIGS. 1 and 3 the distractor sleeve (18) has two pairs of recesses (29) with which the distraction locks (32) are designed to mate. Each recess (29) is formed having a first zone with a depth such that the gripper flanges (36) of a distraction lock (32) must yield slightly to pass thereover, this zone being nearer the top of the distractor sleeve (18). A second zone (31), slightly deeper into the distractor sleeve (18), is separated by a palpable line of demarcation visible in FIGS. 1 and 3 and lies closer to the bottom of the distractor sleeve (18). The gripper flanges (36) "snap" into the lower, deeper portion of their respective recesses (29) when a distraction lock (32) is installed. In this manner, the distraction lock (32) is securely held in place until or unless pried from the distractor sleeve (18).

An alternative embodiment of the distractor sleeve (18) (not shown in the drawings) incorporates multiple pairs of recesses (29) and associated holes (28) near one end of the distractor sleeve (18). Such a distractor sleeve (18) may be shortened using a hack saw at the time of surgery to shorten the starting, most retracted overall length for the thoracodorsal distractor (10) leaving a fully functional distractor sleeve end having the necessary pair of recesses (29) and hole (28). When shortening this embodiment of the distractor sleeve (18), the distractor sleeve (18) is simply cut at a point between adjacent pairs of recesses (29) and the cut end is then smoothed using a file. Such an alternative embodiment of the distractor sleeve (18) permits its use in situations which otherwise would require the manufacture of a shorter distractor sleeve (18). Wider applicability for any one component of Applicant's invention has obvious financial benefits to recipient patients.

The holes (26) in distractor shaft (16a) in the preferred embodiment for use in very young children have been spaced in 10mm intervals in anticipation of the likely growth intervals which will indicate an adjustment of the thoracodorsal distractor (10). Such spacing is in recognition of the fact that only slight misalignment of the spinal column can result in discomfort and possible spinal cord injury.

Referring principally to FIGS. 2 and 7, both the proximal distractor sleeve carriage attachment (14) and the distractor shaft carriage attachment (16b) (of the simplest embodiment of the thoracodorsal distractor (10)) include two rods (20) at their respective ends. The rods (20) are round in cross section. The rods (20) have a cross sectional diameter of 2mm in the preferred embodiment.

The rods' (20) round cross sectional shape was chosen as a means for minimizing the biological trauma to the periosteum of the ribs (12) and to the inferior surfaces of the ribs (12) where the rods (20) have their primary contact therewith (to be discussed in more detail hereinafter).

The specific 2mm diameter of the rods (20) was chosen after numerous alternative specifications were tested. A 2mm diameter of CP Titanium has proven to provide the optimum balance between the flexibility necessary for safe manipulation during implantation and strength necessary for post-implantation stability. No other material tested in a 2mm rod configuration and no other dimension in CP Titanium provided the preferred characteristics for the rods (20).

The rods (20) of the preferred embodiment are 76mm in length. This length has been shown through experimentation to provide a quite acceptable degree of surplus length to facilitate the needed manipulation during implantation both to circumvent the natural ribs (12) at the basic level, as well as to adjust the orientation and position of the loops formed from the rods (20) in determining the over-all orientation of the thoracodorsal distractor (10) within the patient. The indicated length does not, however, introduce excessive length which would impede maneuvering during implantation and require excessive bending to avoid surrounding tissues.

Referring principally to FIG. 7, the rods (20) are during the implantation procedure manipulated by the surgeon to circumvent the appropriate natural rib (12). The path of the rods (20) about the natural rib (12) is essentially circular when properly implanted, even though the rib would be better described as oblong. This is an important aspect of practicing Applicant's invention for

several independently significant reasons. The circular circumvention permits the carriage attachments (14) and (16b) to pivot relative to the natural ribs (12). This is important, in part, because the carriage attachments (14) and (16b) change orientation relative to the ribs (12) to which they are attached as the length of the thoracodorsal distractor (10) is changed subsequent to implantation.

The ability of the carriage attachments (14) and (16b) to pivot is further important in allowing the thoracodorsal distractor (10) to partially accommodate traumatic force which may occur in falls, etc. while not transferring the force to the natural ribs (12) in a manner which would likely fracture the natural ribs (12) or damage the spine to which the distractor (10) is so closely attached. If the carriage attachments (14) and (16b) were rigidly attached to natural ribs (12), the carriage attachments (14) and (16b) would apply a possibly damaging torque to the natural ribs (12) in response to a traumatic force to the distractor shaft (16a) and/or distractor sleeve (18). This is substantially avoided by the circular path of circumvention suggested herein. Also, the relatively loose circumvention of the natural ribs (12) tends to "cage" the rib, not clamp it, obviating the danger of rib ischemia at the site of contact between the rods (20) and the natural rib (12) surface. Still further, the gentle movement permitted by the preferred mode of attachment for the thoracodorsal distractor (10) and brought about by normal movement of the recipient has the tendency to promote work hypertrophy thereby actually strengthening the natural rib (12).

When the thoracodorsal distractor (10) is properly implanted and adjusted, the rods' (20) principal contact with the natural ribs (12) are to inner surface areas of the natural ribs (12) relative to the intervening chest

wall defect. In this manner, the rods (20) "cradle" the natural ribs (12) at a point of minimum contact as opposed to deleteriously compressing them.

The rods (20) number two for each of the carriage
5 attachments (14) and (16b) in satisfaction of some of Applicant's material objectives in designing the preferred embodiment. Most notably, dual attachment sites for the carriage attachments (14) and (16b), as opposed to a singular attachment site, provide substantial rotational
10 stability for the thoracodorsal distractor (10). By way of comparison, a single site of attachment will do little to stabilize the thoracodorsal distractor (10) against even minor deflective forces while a dual attachment quite ably resists such force. Also, the cumulative mass of
15 titanium needed for strength of the attachment to the natural ribs (12) can be divided between the two rods (20) as opposed to being embodied in a single, larger rod. Such a single rod would be too stiff to safely manipulate during implantation if it incorporated the same quantum of
20 titanium as is divided between the two rods (20) of each carriage attachment (14) and (16b) of the preferred embodiment.

It is noted that the use of three or more rods (20) is not recommended because of the associated consumption
25 of surface space on the natural ribs (12) and the minimal additional stability which would be achieved. Because a plurality of thoracodorsal distractors (10) will be required in most situations requiring any use of the thoracodorsal distractor (10), conservation of natural rib
30 (12) surface space is desired.

A sample surgical procedure involved in implantation of the thoracodorsal distractor is outlined as follows:

Three 4 cm longitudinal skin incisions are required. The first incision is made at the

base of the thoracic spine. It is carried down to the paraspinal muscles overlying the posterior spinous processes of the thoracic spine. The soft tissues and the osseous elements of the spine are not violated in order to minimize the risk of accidental spine fusion. Dissection then continues laterally over the top of the paraspinous muscles to avoid denervation of the muscle. This carries the incision deep to the medial rib at its intersection with the transverse process.

The selected point of rib attachment is chosen and a periosteum incision made over the rib. The retractors are inserted to elevate the periosteum off the rib and this protects both the inferior neurovascular bundle of the rib and also the underlying lung. Pneumothorax is the only serious complication of the operative procedure and the risk is minimal with subperiosteal direction which orthopedists are very familiar with. Once the rib site is prepared, then a second and third site is prepared both at the central portion of the thoracic spine and at the proximal portion of the spine. The surgical sites involve reflection of the trapezius muscles laterally from the central and inferior operative sites, and in addition, the levator scapuli and rhomboid muscles are reflected laterally at the superior prosthesis attachment site. Next, a malleable rod of similar dimensions of the prosthesis is threaded carefully from the central operative exposure site distally, until visible in the distal site.

5 A similar rod is then threaded through the central site proximally. A thick plastic tube is then anchored to the first malleable rod at the distal site and then threaded up to the central site. Next, the plastic tube is then anchored to the proximal malleable rod and threaded out to the proximal operative site. Next, the prosthetic sleeve and shaft are attached to the plastic at the inferior site and manipulated through both twisting and gentle pushing up the paraspinal gutter until it is in the proper position for implantation. The plastic tube is pulled during this maneuver and it guides the prosthesis through the hole made by the malleable rods and prevents the proximal end of the prosthesis from accidental plunging into the thorax and causing either cardiac or pulmonary damage (one known complication of subcutaneous threading of a straight Harrington or Moe rod in this fashion is plunging of the sharp straight end of the rod into the chest as it attempts to pass over the apex of the thorax of the central thoracic spine). Once in position, the rib carriages are engaged to the proximal and distal ribs exposed by prior subperiosteal dissection. If a titanium sling loop is necessary at the central incision, then it threaded around a prepared rib and loosely around the prosthetic sleeve.

30

Referring to FIGS. 9, 10, 11 and 12, an alternative (and preferred) proximal fixation device (the auto-lock rib carriage) is identified generally by the reference numeral (110). Auto-lock rib carriage (110) includes an

approximately 3/4 circle under carriage ring (112) with a slidably journaled over carriage ring (114) movably engaged therewith. As is clear comparing FIGS. 9 and 10, simply rotating the over carriage ring (114) relative to the under carriage ring (112) forms (or alternatively opens) a fully enclosed circle.

Use of the auto-lock rib carriage (110) greatly simplifies attachment of a thoracodorsal distractor as compared with use of rods (20) as described above with reference to distractor (10). One simply positions the auto-lock rib carriage (110) in proper position and orientation relative to the designated proximal attachment rib (12), moves the over carriage ring (114) so as to close the circle about the rib (12), and locks the over carriage ring (114) in place.

Referring principally to FIGS. 9, 10 and 13, over carriage ring (114) exhibits a lip (118) which is sized for reception into a slot (120) formed in the base (122) of the auto-lock rib carriage (110). A saddle lock (124) with a locking cam (126) is designed to lock into position on the base (122) at an interlock site (128) whereby the locking cam (126) securely holds the over carriage ring (114) in its closed position.

Referring principally to FIGS. 9, 10, 11 and 12, the under carriage (112) includes a carriage shaft (130) a terminal portion of which is formed into a spline (132). In the embodiment of a thoracodorsal distractor which employs the auto-lock rib carriage (110) (not shown in the drawings), the proximal end of the distractor sleeve (18) is formed into a socket which is suitably contoured to effectively mate with the spline portion (132) of the carriage shaft (130). This arrangement, among other benefits, allows the user to orient the auto-lock rib carriage (110) in any of numerous positions relative to

the distractor sleeve (18). This is a particularly important benefit in light of the potentially unpredictable course and orientation of ribs (12) in a scoliosis patient to which a user may want to attach the 5 distractor at the proximal end.

Referring principally to FIGS. 9 and 10, carriage shaft (130) exhibits a shaft lip (134) which, in cooperation with a carriage shaft lock (136), serves to securely lock the auto-lock rib carriage (110) and the 10 suitably modified distractor sleeve (not separately shown in the drawings) together. The carriage shaft lock (136) having, as it does, a shaft lock pin (138), is designed to snap into position relative to a recipient hole, analogous to hole (28) as described above (not shown in the 15 drawings) on the distractor sleeve (18) in the same manner as the distraction locks (32) as described above. The carriage shaft lock (136) also exhibits a shaft lip clamp (140) which is sized and shaped to juxtapose the carriage shaft (130) on the side of the shaft lip (134) opposite 20 the spline (118). The recipient hole in distractor sleeve (18) is positioned relative to the proximal terminus of the distractor sleeve (18), and the such that the shaft lip clamp (140) is positioned relative to the shaft lock pin (138) such that, when the carriage shaft (130) is 25 fully received within the socket of the distractor sleeve (18), and the carriage shaft lock (136) is pressed into position, the interaction of the shaft lip clamp (140) and the shaft lip (134) prevents separation of the auto-lock rib carriage (110) from the distractor sleeve (18).

30 Referring principally to FIGS. 9 and 10, to prevent lateral shifting of the auto-lock rib carriage (110) relative to the natural rib (12) to which is attached, a rib spike (142) is positioned on the base (122) of the auto-lock rib carriage (110) projecting into the circle

defined by the over carriage ring (114) and the under carriage ring (112). While this will retard some movement of a thoracodorsal distractor relative to a natural rib (12) to which it is attached, and will, therefore, reduce
5 some of the potential energy dissipation as discussed above, the ability of the natural rib (12) to oscillate within the confines of the circle defined by the over carriage ring (114) and the under carriage ring (112) in response to everyday forces will dissipate energy and
10 promote work hypertrophy to a very beneficial degree as compared with any imaginable rigidly fixed systems.

Referring principally to FIGS. 6, 15 and 16, relevant portions of a preferred embodiment of a thoracodorsal distractor (210) (except in FIG. 6 wherein it is reference
15 numeral (10) as relates to the distal attachment position and attachment means) is depicted. Because of the desired orientation of the thoracodorsal distractor relative to the spinal column, Applicant has determined that the distal or inferior attachment could be to the sacrum (212)
20 as opposed to a lower rib in the event of lumbar scoliosis. The preferred attachment means is that of a saddle bracket (214) which overlies a portion of the sacrum (212). A rod (216) extends through appropriately positioned holes in the saddle bracket (214) and through
25 the sacrum (212). The distal end of the distractor shaft (218) of this embodiment is formed as the male portion of a pestle joint (220), the female portion being fashioned from the portion of the saddle bracket (214) opposite the sacrum (212). The pestle joint (220) allows pivoting of
30 the distractor shaft (218) within a relatively wide cone-shaped range of motion relative to the sacrum (212). This, in turn, serves to accommodate shock to the distractor (210) and to allow a certain enhanced degree of motion for a recipient, while still maintaining the

prescribed longitudinal length of the distractor (210) for exerting the desired distractive or compresses forces on the involved skeletal components.

Referring principally to FIG. 16, the pestle joint 5 (220) is fitted with a debris cover (222) to prevent accumulation of debris inside the joint's socket space and to thereby insure continued effective operation of the joint.

Referring principally to FIGS. 17, 18, 19, 20, 21 and 10 23, relevant portions of a preferred embodiment of a thoracodorsal distractor (310) as relates to the means for expanding and contracting the over-all length of the device is shown. The principle object served by this aspect of the system is to allow for post-implantation 15 length adjustment by way of very simple, out-patient surgery.

The expansion/retraction system provided in FIGS. 17, 18, 19, 20, 21 and 23 is based, in part, upon a rack and pinion-like system. A portion of the internal margin of 20 the distractor sleeve (312) is formed into a gear track or "rack" (314). The rack (314) is positioned superior to the channel through which the distractor shaft (318) extends and inferior to the top face (319) of the distractor sleeve (312) (partially removed in FIG. 18 for 25 visibility.

A screwdriver-like probe (316) (see FIG. 21) exhibits a gear (320) at its distal end which gear (320) is sized and configured to mate with the teeth of rack (314). Extending axially from exposed face of the gear (320) is 30 a pin (322) which is sized and shaped for insertion into one of the distraction holes (324) in the distractor shaft (318).

The top face (319) of the distractor sleeve (312) exhibits a three lobed orifice (326), each lobe of which

is sized for receiving gear (320) therethrough for engagement with the rack (314). The margins of each lobe of orifice (326) is also threaded for threadingly mating with a locking system (to be described later). The lobes 5 of the orifice (326) are configured whereby the gear (320) may be engaged or disengaged from the rack (314) of the distractor sleeve (312) and from the distractor shaft (318) at 0.5 cm intervals.

Operation of the expansion/retraction system of FIGS. 10 17, 18, 19, 20, 21 and 23 merely involves inserting the gear (320) of the probe (316) through the medial-most lobe of orifice (326), axially rotating the probe (316) in a counter-clockwise direction (from the perspective of the user), and removing the probe (316) from either of the two 15 adjacent lobes of orifice (326) (depending on the extent of expansion desired). Of course, if more than 1.5 cm of expansion is desired, the process can be repeated.

Referring to FIGS. 24, 25 and 26, Applicant provides a ratchet mechanism (330) for affixation to the distractor 20 sleeve (312). The ratchet mechanism (330) includes dual leaves (332) each of which exhibits a locking cam (334) sized and shaped for extending into one of the distraction holes (324) in the distractor shaft (318) (as allowed through a suitably sized and shaped portal in the top face 25 (319) of the distractor sleeve (312).

Referring principally to FIG. 24, the locking cams (334) are each contoured such that, when the ratchet mechanism (330) is oriented as shown in FIG. 24, they allow expansion, but not contraction of the distractor 30 (310). In other words, each locking cam (334) exhibits a flattened face which is oriented toward the proximal end of the distractor (310), but an obliquely oriented face which is oriented toward the proximal end of the distractor (310). The operation and effect of the ratchet

mechanism (330) is self evident from the figures.

Referring principally to FIG. 17, as with the distraction locks (32) as described above, the ratchet mechanism (330) is configured to snap onto the under
5 surface of the prosthesis into indentations (338) formed on the outer surface of the distractor sleeve (312). This design permits a user during initial implantation to freely move the distractor (310) and only after reaching the appropriate minimal length thereof, affixing the
10 ratchet mechanism (330) to prevent inadvertent contraction.

Referring principally to FIGS. 27, 28, 29 and 30, Applicant's design further includes a locking system for use with the just-described expansion/retraction system.
15 This system centers on a locking disk (340) which includes a locking disk pin (342), a free gear (344), a lock washer (346), and a threaded cap disk (348). The threaded cap disk (348) has a hexagonal recess (350) in its exterior face for mating with a complimentarily shaped and sized
20 tip (362) of a hex screwdriver (352). From the base of the hexagonal recess (350) is a threaded column (354) which is sized for threadingly mating with a threaded rod (356) which extends axially through the center of the hex screwdriver (352). The locking disk pin (342) is, in the
25 preferred embodiment, an integral part of the threaded cap disk (348) and includes an annular gear-retaining bead (360) for maintaining the free gear (344) thereon with the lock washer (346) intervening the free gear (344) and the interior face of the threaded cap disk (348). The locking
30 disk pin (342) is sized and shaped for extending into one of the distraction holes (324) in the distractor shaft (318) and is tapered so as to relieve tension from the ratchet mechanism (330) between adjustments of the distractor (310).

Once the distractor (310) is adjusted for length as desired as described above, a user of Applicant's system secures the threaded cap disk (348) to the hex screwdriver (352) by use of the threaded rod (356). The user then
5 directs the locking disk (348) toward the medial most lobe of the orifice (326) on the distractor sleeve (312) and appropriately rotates the hex screwdriver (352) until the threaded cap disk (348) is fully seated in the orifice (326) whereby the locking disk pin (342) extends into the
10 underlying hole (324) in the distractor shaft (318), the free gear (344) is mated with the rack (314) of the distractor sleeve (312) and lock washer (346) is compressed to the point where the threaded disk cap (348) will not accidentally become disengaged from the
15 distractor sleeve (312). The user then disengages the hex screwdriver (352) from the threaded cap disk (348) and closes the puncture wound used to access the distractor (310).

Although the invention has been described with
20 reference to specific embodiments, this description is not meant to be construed in a limited sense. Various modifications of the disclosed embodiments, as well as alternative embodiments of the inventions will become apparent to persons skilled in the art upon the reference
25 to the description of the invention. It is, therefore, contemplated that the appended claims will cover such modifications that fall within the scope of the invention.

I claim:

1. A thoracodorsal distractor comprising:
 - a shaft member comprising a plurality of members movably attached to each other in a manner whereby said shaft member is adjustable in length, said shaft member exhibiting a complex curve in substantially a single plane for conforming to differing curvatures of a dorsal continuum of a human recipient; and
 - stabilizing means for securing said thoracodorsal distractor to skeletal components of a recipient of said thoracodorsal distractor.
2. The invention of Claim 1 wherein said shaft member comprises first and second distractor members, said first thoracodorsal distractor member being telescopically received within said second thoracodorsal distractor member.
3. The invention of Claim 2 wherein said stabilizing means comprises a plurality of rods, at least one said rod being affixed at respective outer ends of said first and second thoracodorsal distractor members, said rods being of a malleable material and of a length whereby said rods may be manipulated to circumvent a natural rib of said recipient and thereby secure said thoracodorsal distractor within said recipient.
4. The invention of Claim 2 wherein said stabilizing means comprises first and second pairs of rods being respectively affixed to outer ends of said first and second thoracodorsal distractor members, each of said rods being made of a sufficiently malleable material and being of a sufficient length, when measured parallel with the

length of said first and second thoracodorsal distractor members, whereby said rods may be manipulated to circumvent a natural rib of said recipient and thereby secure said thoracodorsal distractor within said recipient.

5. The invention of Claim 4 further comprising means for arresting movement of said first and second thoracodorsal distractor members relative to each other.

6. A method for the manipulation of curvature in a human spine comprising the steps of:

selecting a thoracodorsal distractor comprising:

a shaft member comprising a plurality of members movably attached to each other in a manner whereby said shaft member is adjustable in length; and

stabilizing means for securing said thoracodorsal distractor to skeletal components of a recipient of said thoracodorsal distractor;

affixing a first end of said thoracodorsal distractor to a first said skeletal component on a proximal side of said scoliotic curvature;

affixing a second end of said thoracodorsal distractor to a second said skeletal component on a distal side of said scoliotic curvature; and

adjusting said thoracodorsal distractor so as to exert a first correcting force on said skeletal components whereby said scoliotic curvature is at least partially corrected.

7. The method of Claim 6 wherein said first and said

second skeletal components are ribs, and said thoracodorsal distractor is attached closely adjacent to a recipient's spinal column.

- 5 8. The method of Claim 6 wherein said first said skeletal component is a thoracic rib and said second skeletal component is the sacrum of a recipient of said thoracodorsal distractor.
- 10 9. The method of Claim 7 further comprising the step of affixing a second said thoracodorsal distractor to third and fourth said skeletal components and adjusting said second thoracodorsal distractor so as to exert a second corrective force which is complimentary to said first
15 corrective force.
10. The method of Claim 6 wherein said shaft member exhibits a complex curve in substantially a single plane for conforming to varying curvatures of a dorsal continuum
20 of a human recipient
11. The method of Claim 7 wherein said shaft member exhibits a complex curve in substantially a single plane for conforming to varying curvatures of a dorsal continuum
25 of a human recipient.
12. The method of Claim 6 wherein said shaft member comprises first, second and third distractor members, said first distractor member being telescopically received
30 within said second distractor member and said first and said second distractor members jointly defining an arc of fix radius regardless of the degree to which said first distractor member is received within said second distractor member, said third distractor member being

attached to said second distractor member on an end of said second distractor member opposite where said first member enters said second distractor member, said third distractor member having a third distractor member shaft portion which exhibits a curvature of differing radius than said radius of said arc defined by said first and second distractor members.

13. The method of Claim 7 wherein said shaft member comprises first, second and third distractor members, said first distractor member being telescopically received within said second distractor member and said first and said second distractor members jointly defining an arc of fix radius regardless of the degree to which said first distractor member is received within said second distractor member, said third distractor member being attached to said second distractor member on an end of said second distractor member opposite where said first member enters said second distractor member, said third distractor member having a third distractor member shaft portion which exhibits a curvature of differing radius than said radius of said arc defined by said first and second distractor members.

14. The method of Claim 8 wherein said shaft member comprises first, second and third distractor members, said first distractor member being telescopically received within said second distractor member and said first and said second distractor members jointly defining an arc of fix radius regardless of the degree to which said first distractor member is received within said second distractor member, said third distractor member being attached to said second distractor member on an end of said second distractor member opposite where said first

member enters said second distractor member, said third distractor member having a third distractor member shaft portion which exhibits a curvature of differing radius than said radius of said arc defined by said first and 5 second distractor members.

15. The method of Claim 9 wherein said shaft member comprises first, second and third distractor members, said first distractor member being telescopically received 10 within said second distractor member and said first and said second distractor members jointly defining an arc of fix radius regardless of the degree to which said first distractor member is received within said second distractor member, said third distractor member being 15 attached to said second distractor member on an end of said second distractor member opposite where said first member enters said second distractor member, said third distractor member having a third distractor member shaft portion which exhibits a curvature of differing radius 20 than said radius of said arc defined by said first and second distractor members.

16. An apparatus for reorienting and derotating the human spine comprising:

- 25 a first telescopic element having first attachment means for attachment to a first human rib;
 a second telescopic element, movably receivable within a portion of said first telescopic element and having second attachment means for 30 attachment to a skeletal component other than said first human rib; and
 rib sling means for attachment between said apparatus and said underlying ribs for drawing said ribs near said apparatus;

said first and said second telescopic elements jointly defining a desired contour for human ribs which underlie said apparatus when implanted.

5

17. The invention of Claim 16 wherein said apparatus extends in substantially a single plane, but exhibits varying curvature for conforming to varying curvature of a human chest wall.

10

18. The invention of Claim 16 wherein said first attachment means exhibits two interlocking members which jointly define a substantially circular enclosure for enveloping said first human rib.

15

19. The invention of Claim 16 wherein said second attachment means exhibits two interlocking members which jointly define a substantially circular enclosure for enveloping a portion of said second skeletal component.

20

20. The invention of Claim 16 wherein said second attachment means exhibits a saddle bracket for attachment to the human sacrum.

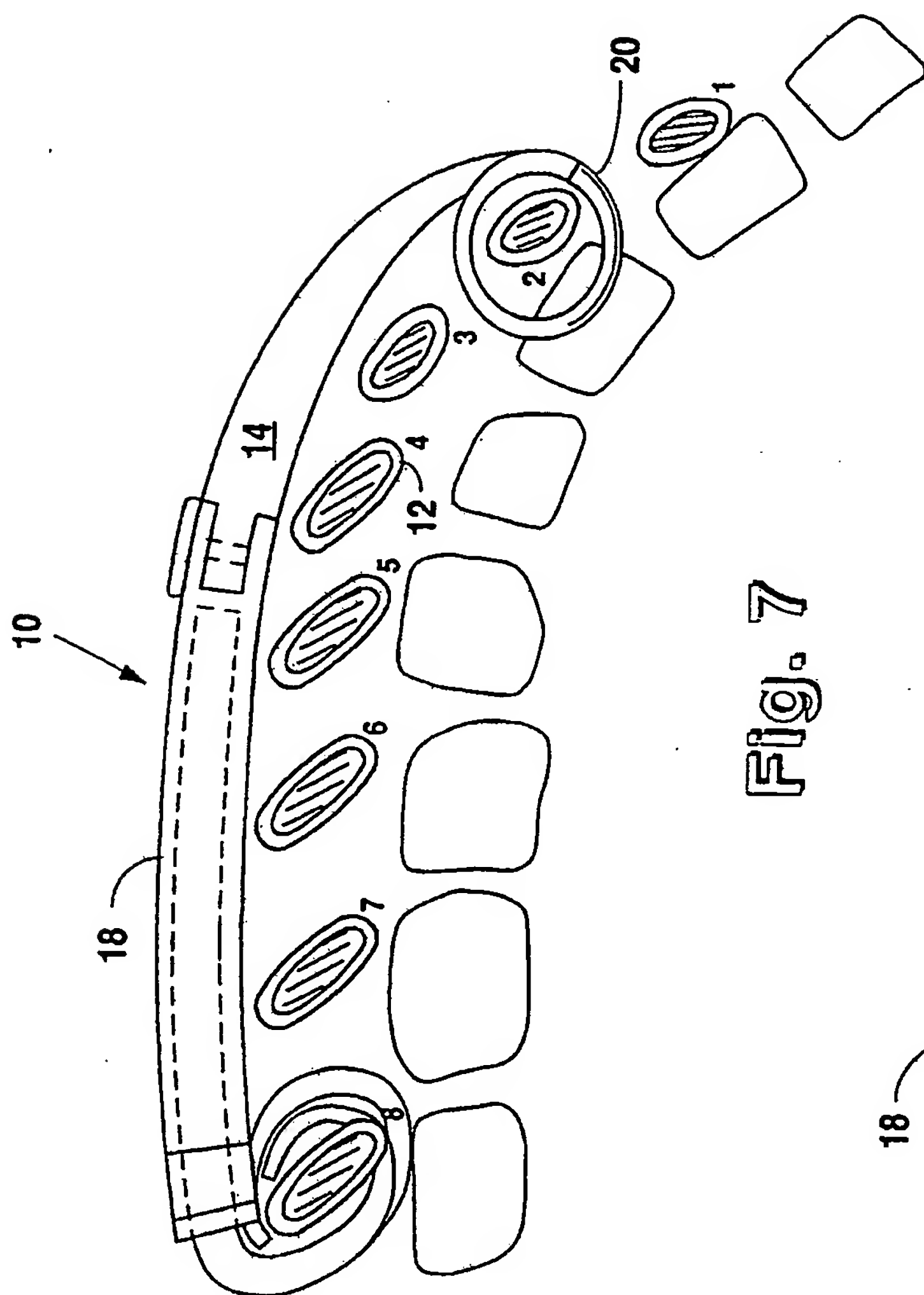


Fig. 7

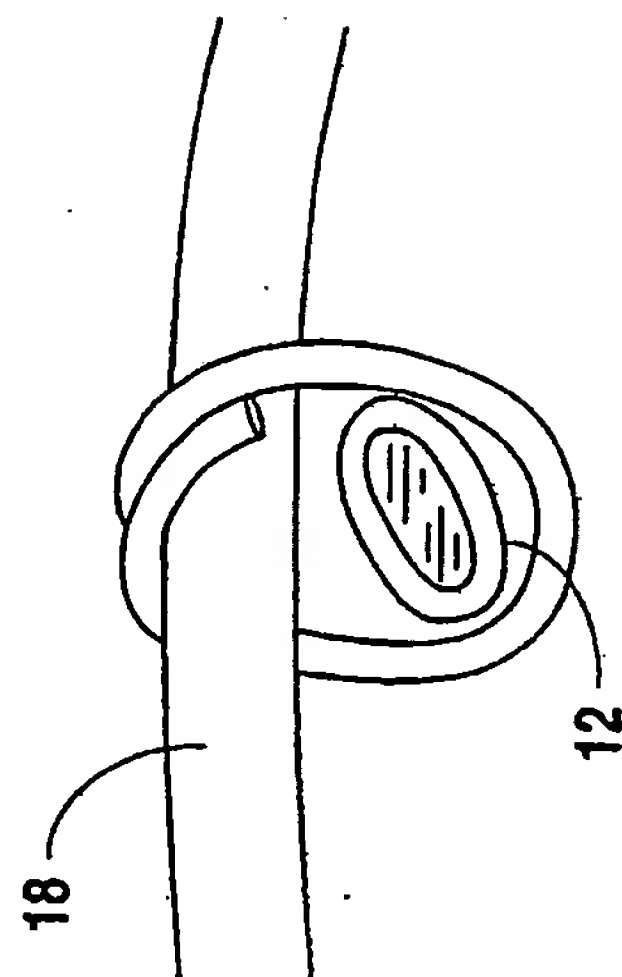


Fig. 8

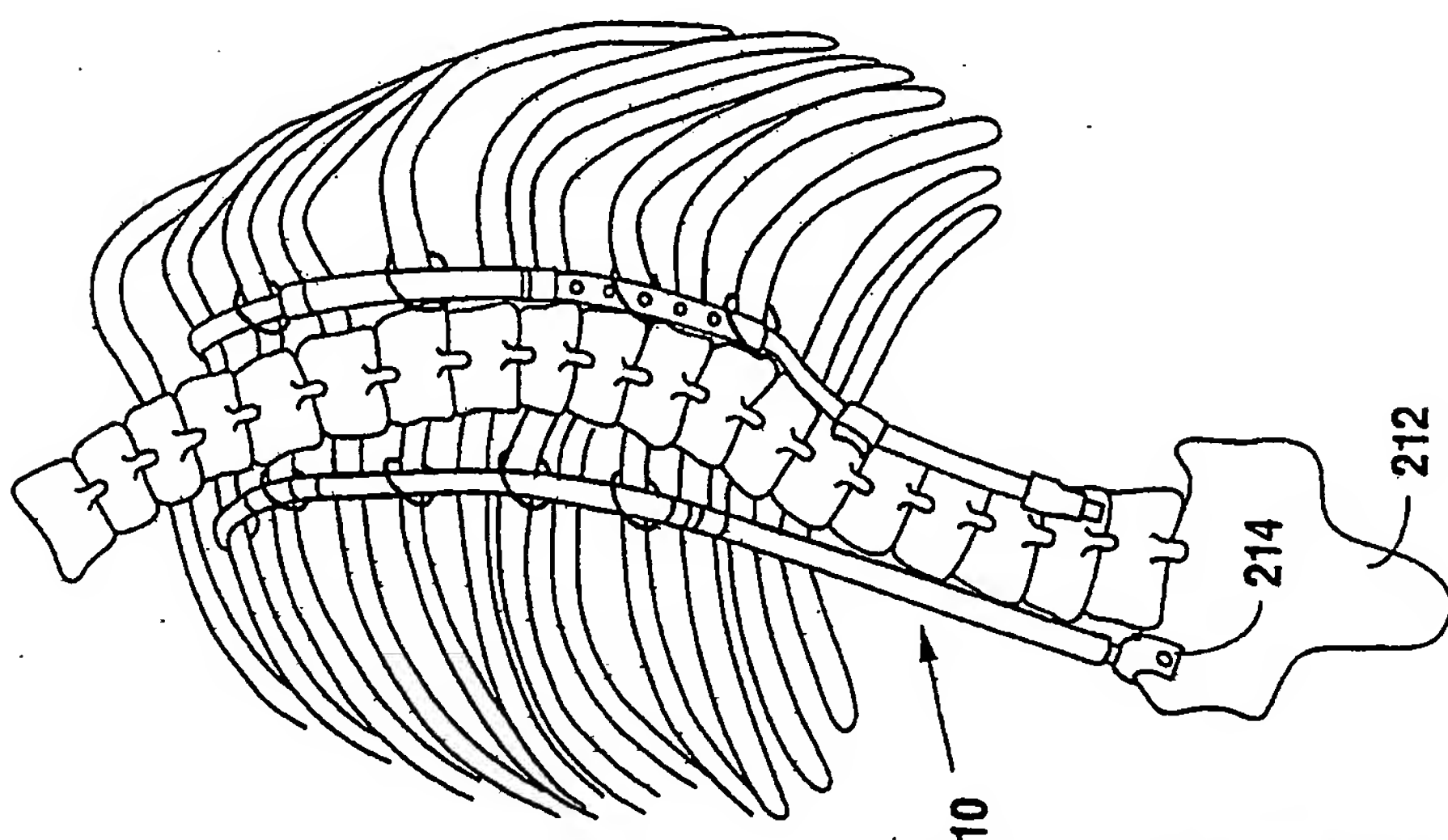


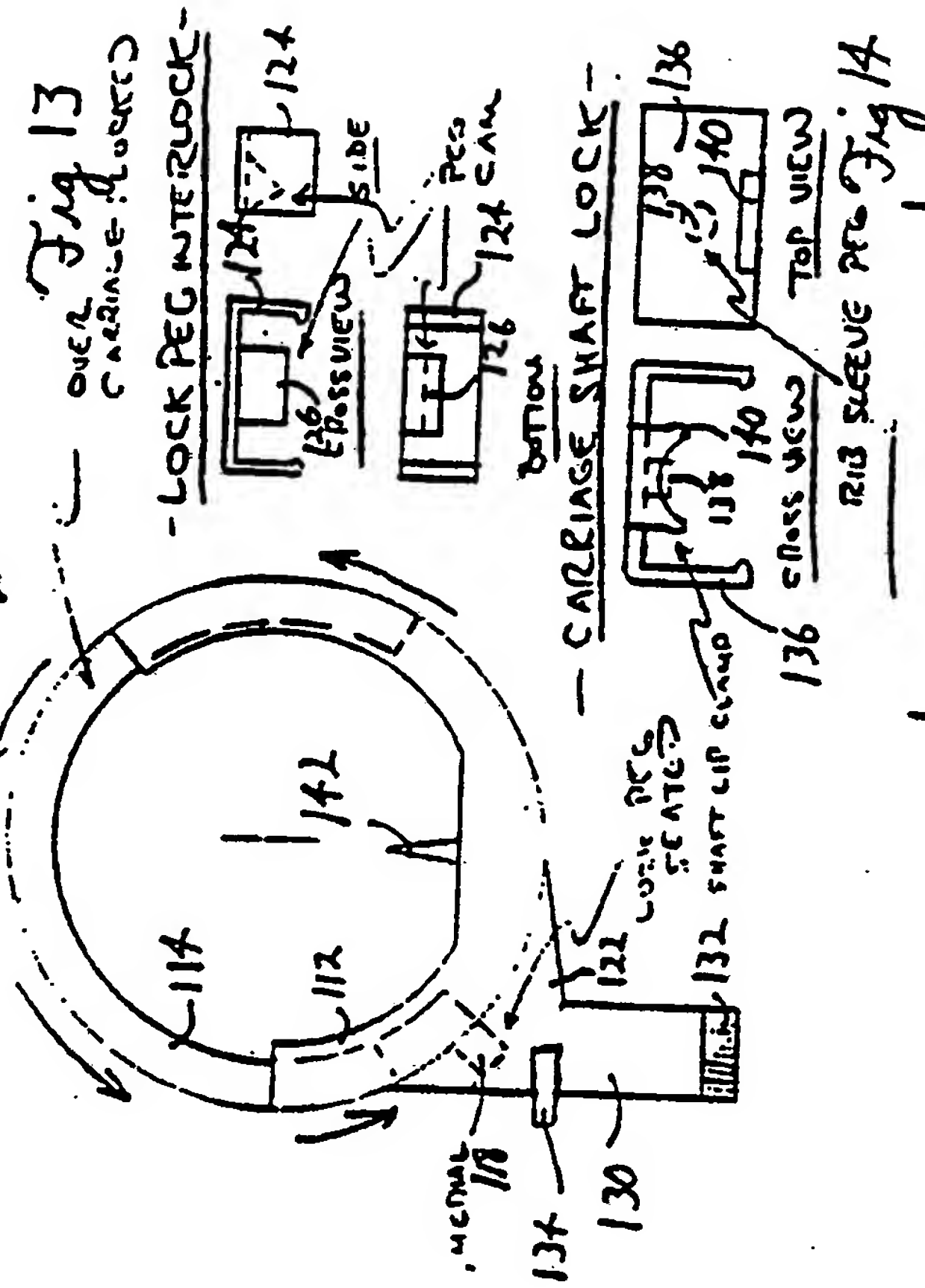
Fig. 9

SUBSTITUTE SHEET

AUTO-LOCK RIB CARRIAGE

(INTERNAL EXPANDABLE PLASTIC RIB)

Fig 10



2126192

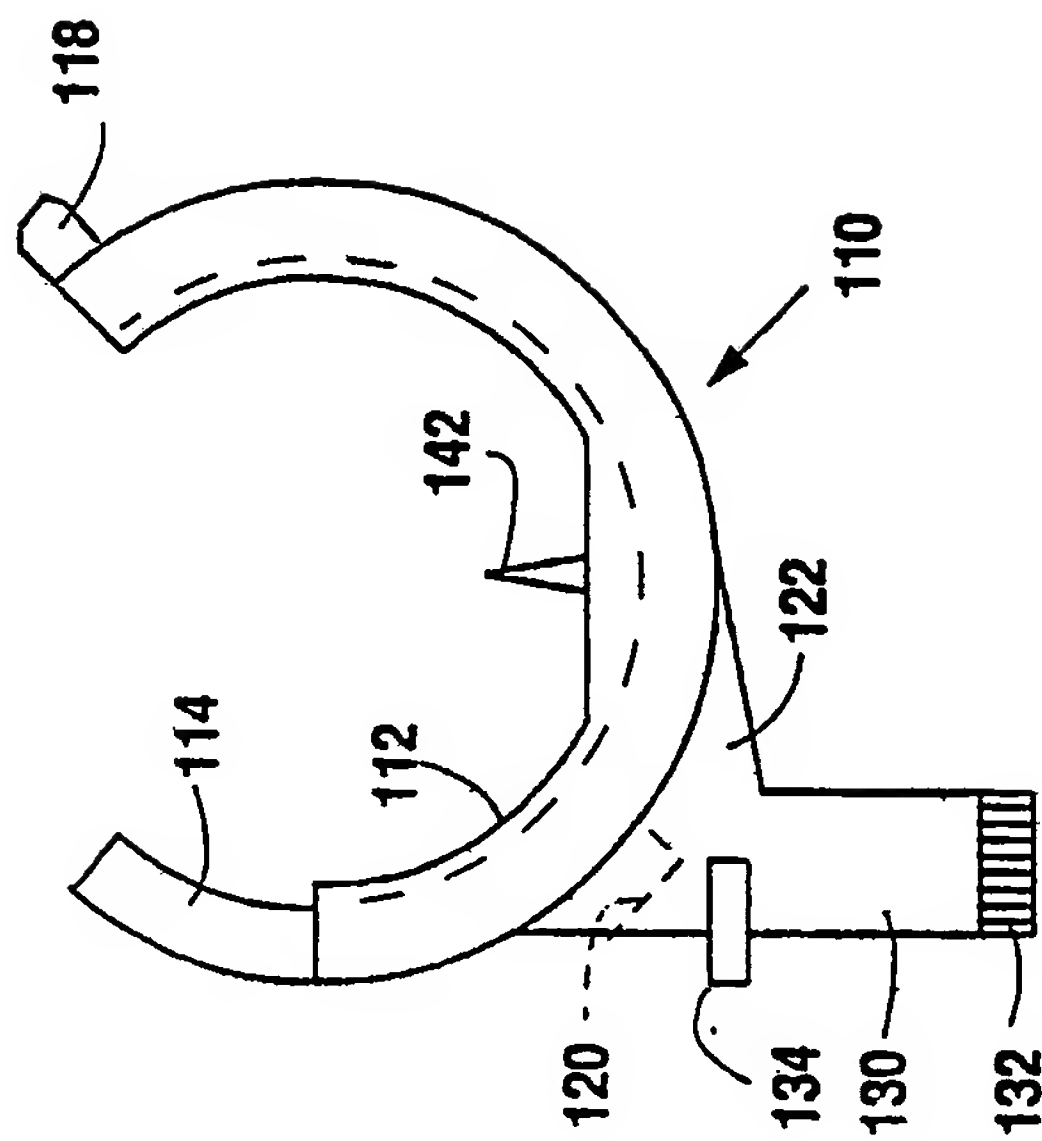


Fig. 9

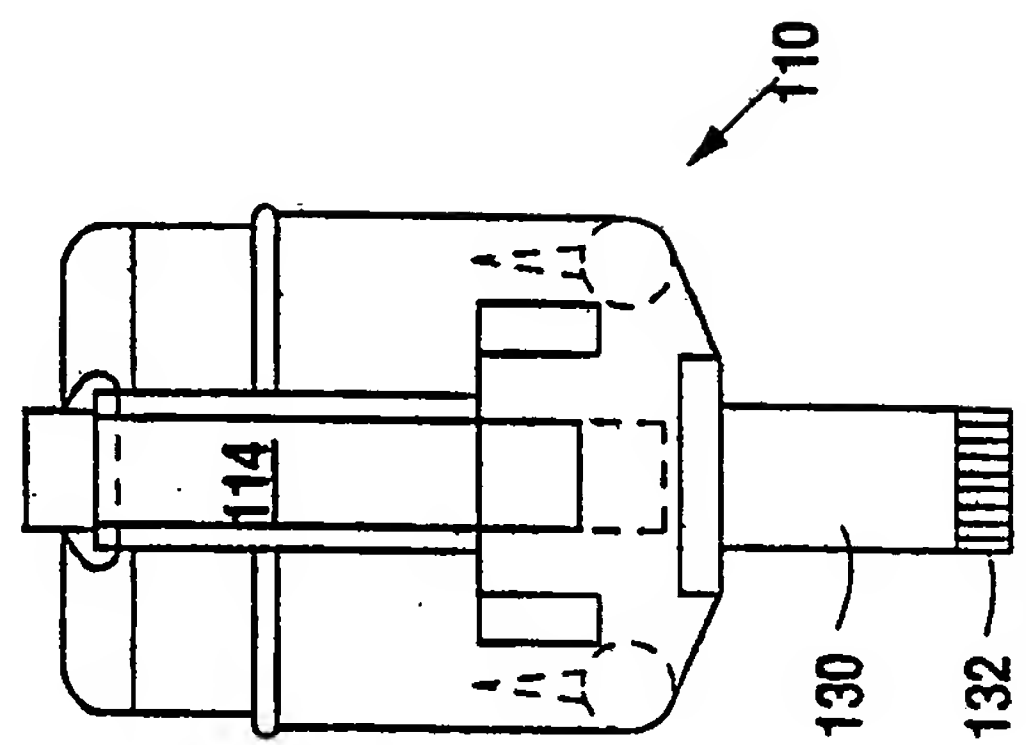


Fig. 11

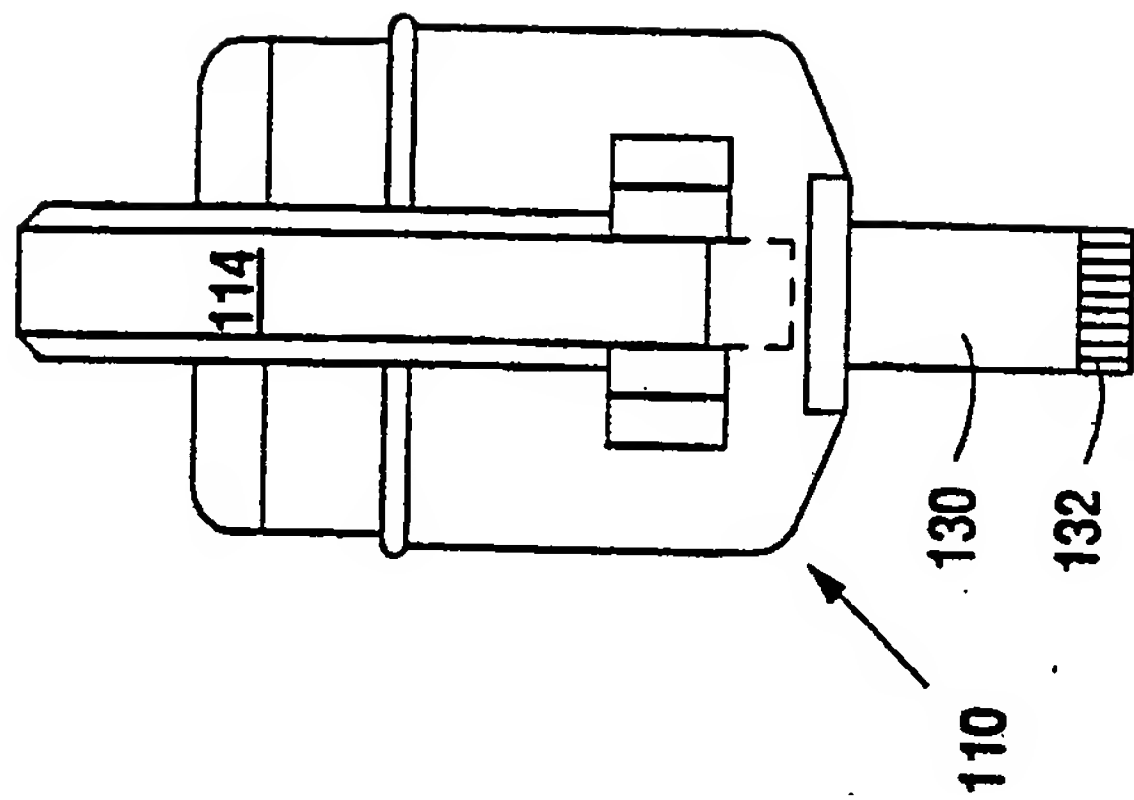


Fig. 12

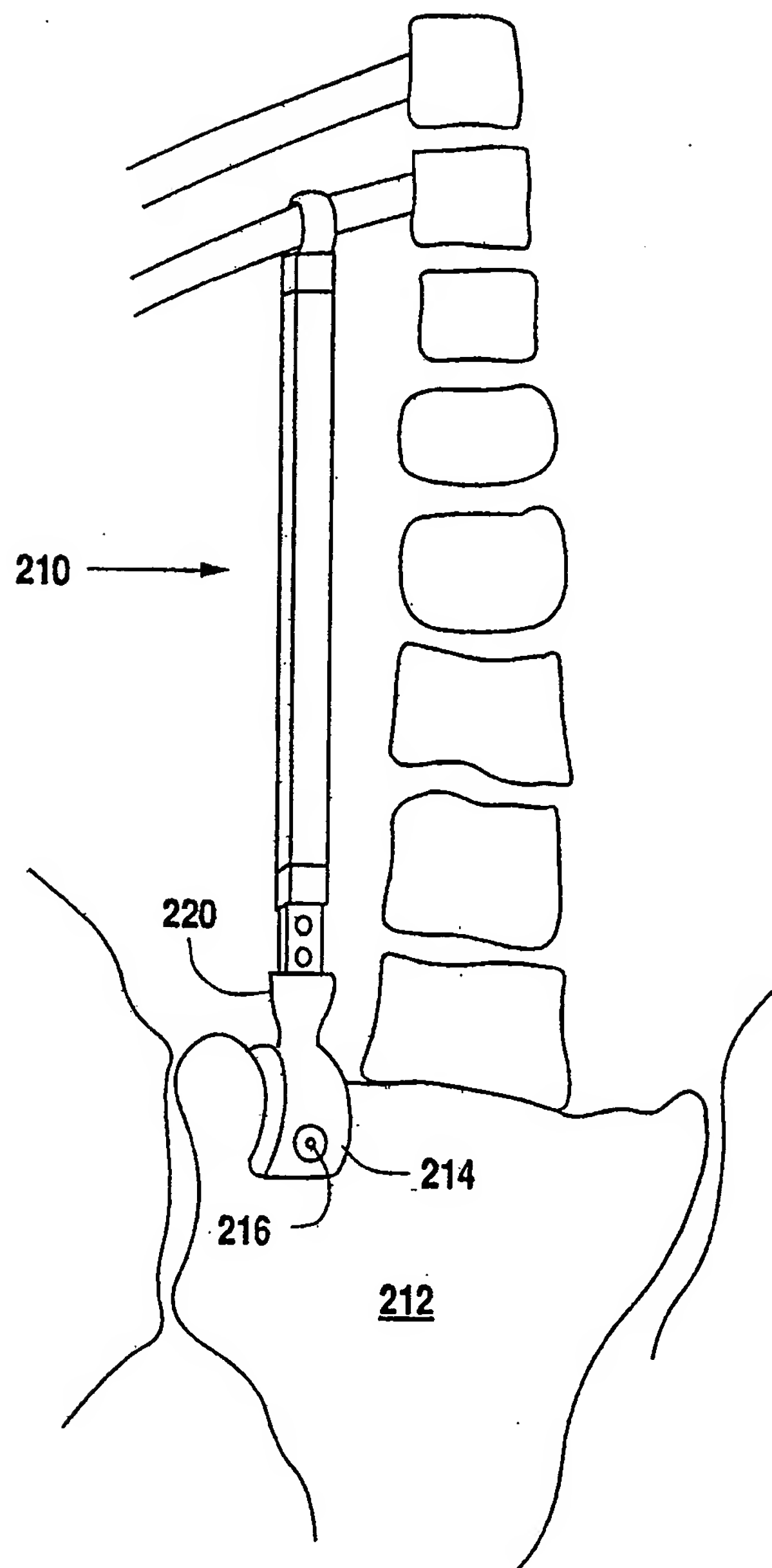


Fig. 15

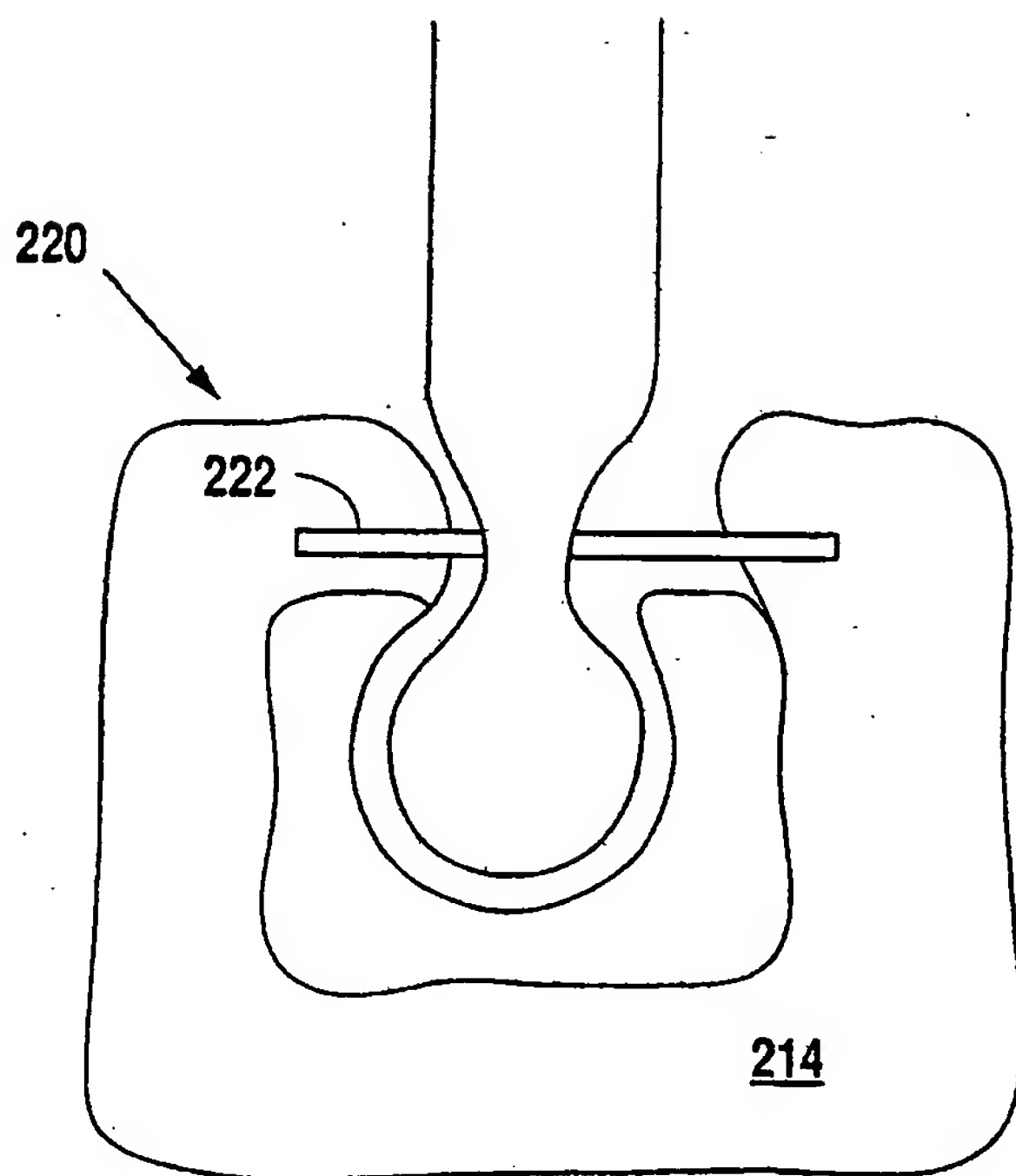


Fig. 16

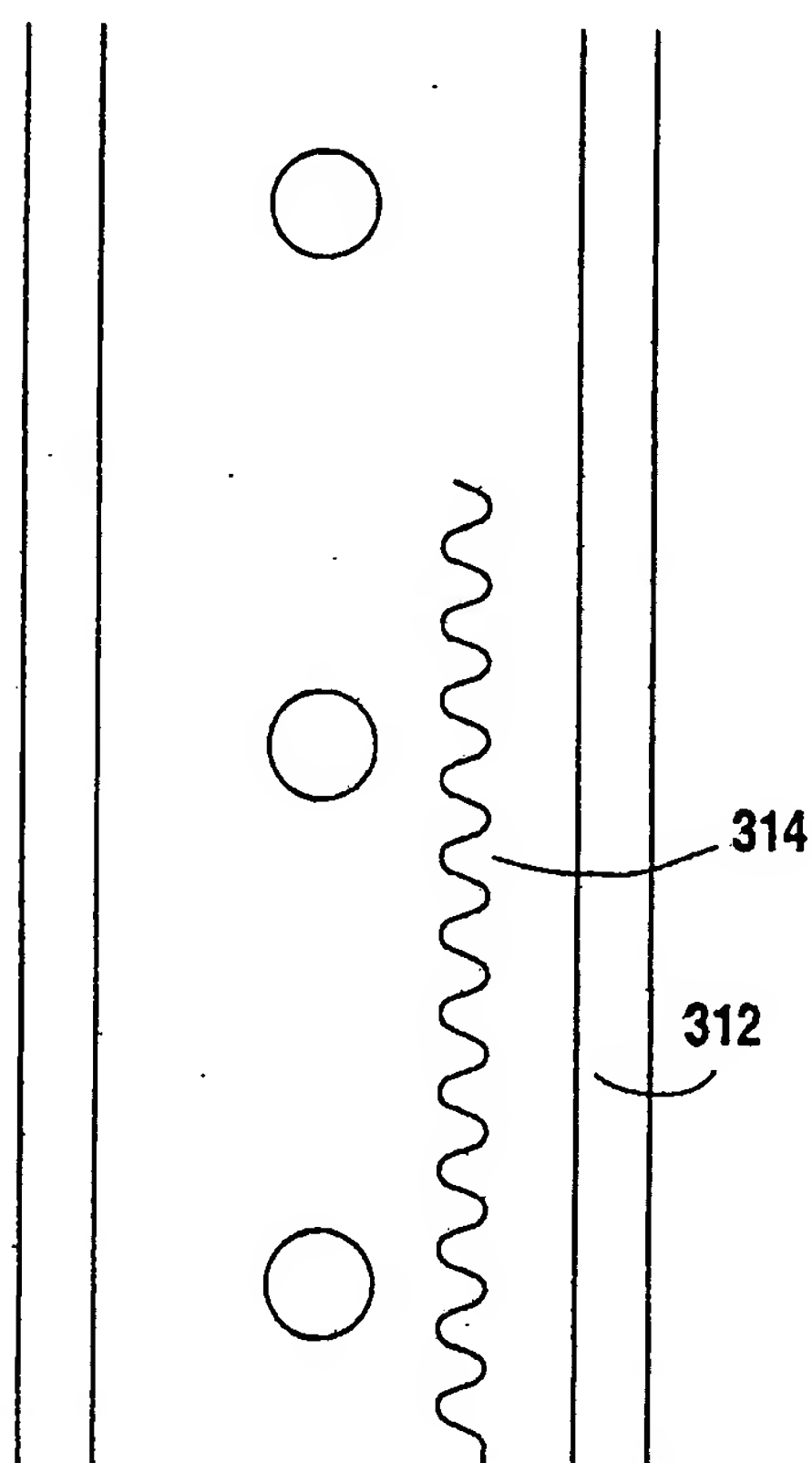


Fig. 19

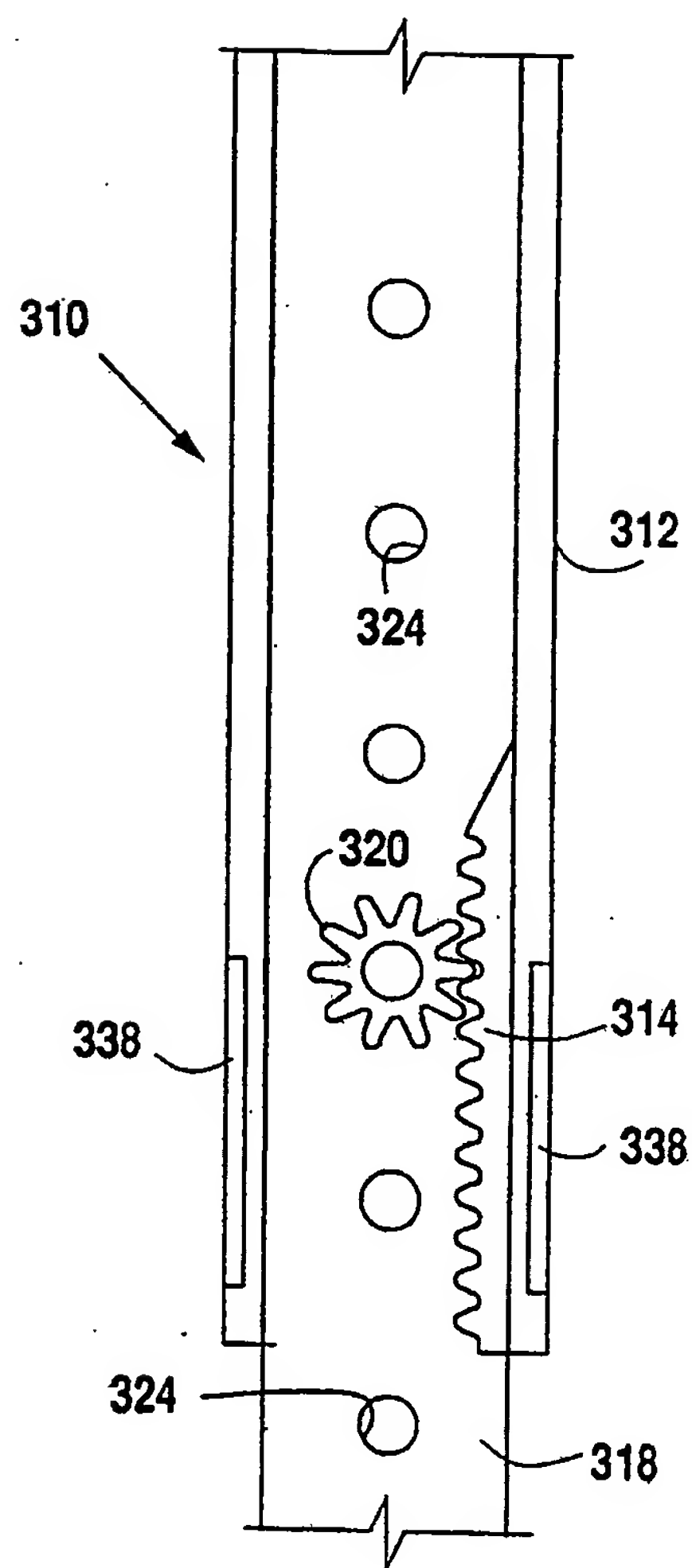
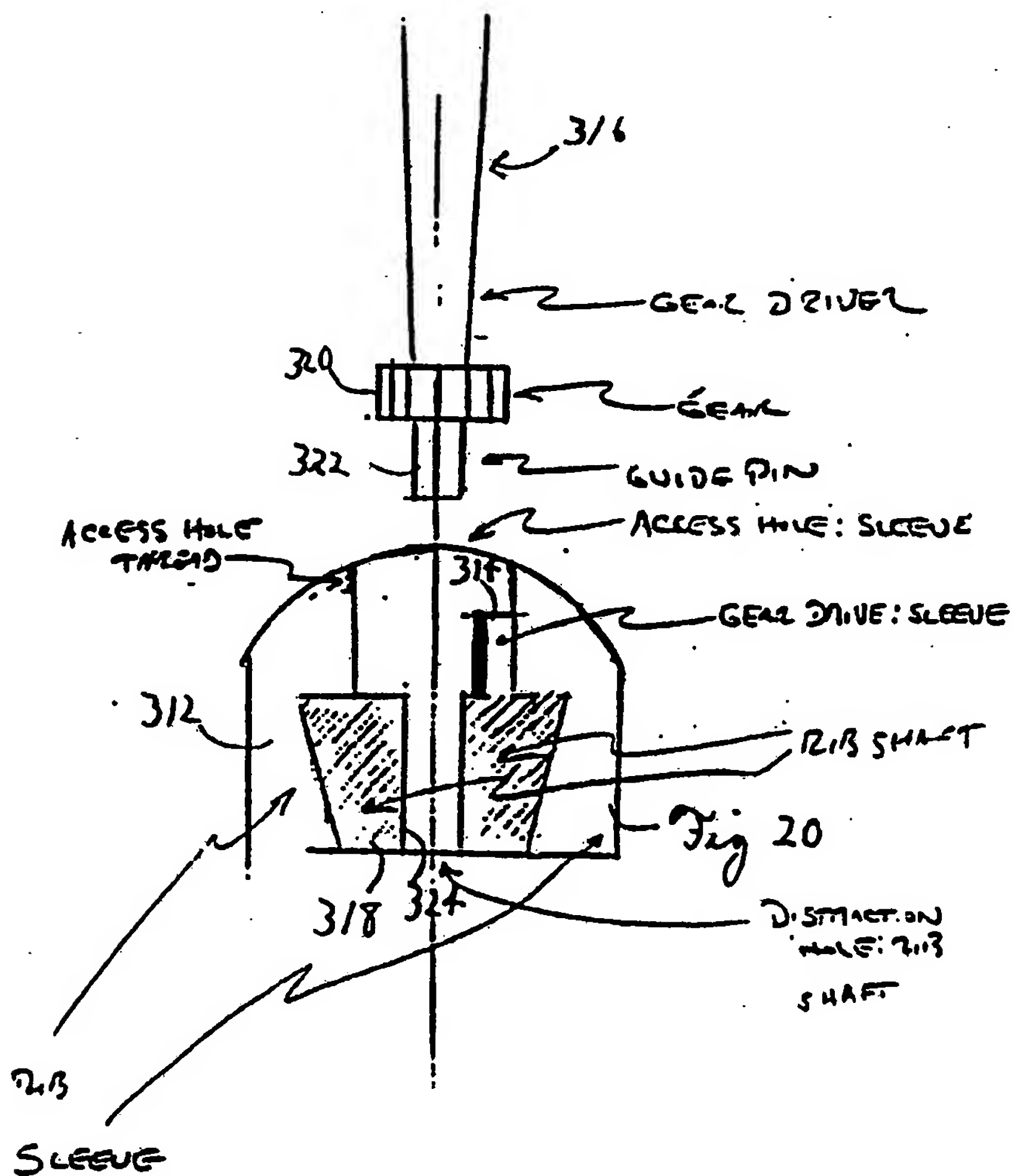


Fig. 17

7/12

GEAR DRIVE
EXPANSION VERTICAL ADJUSTABLE TITANIUM RIB



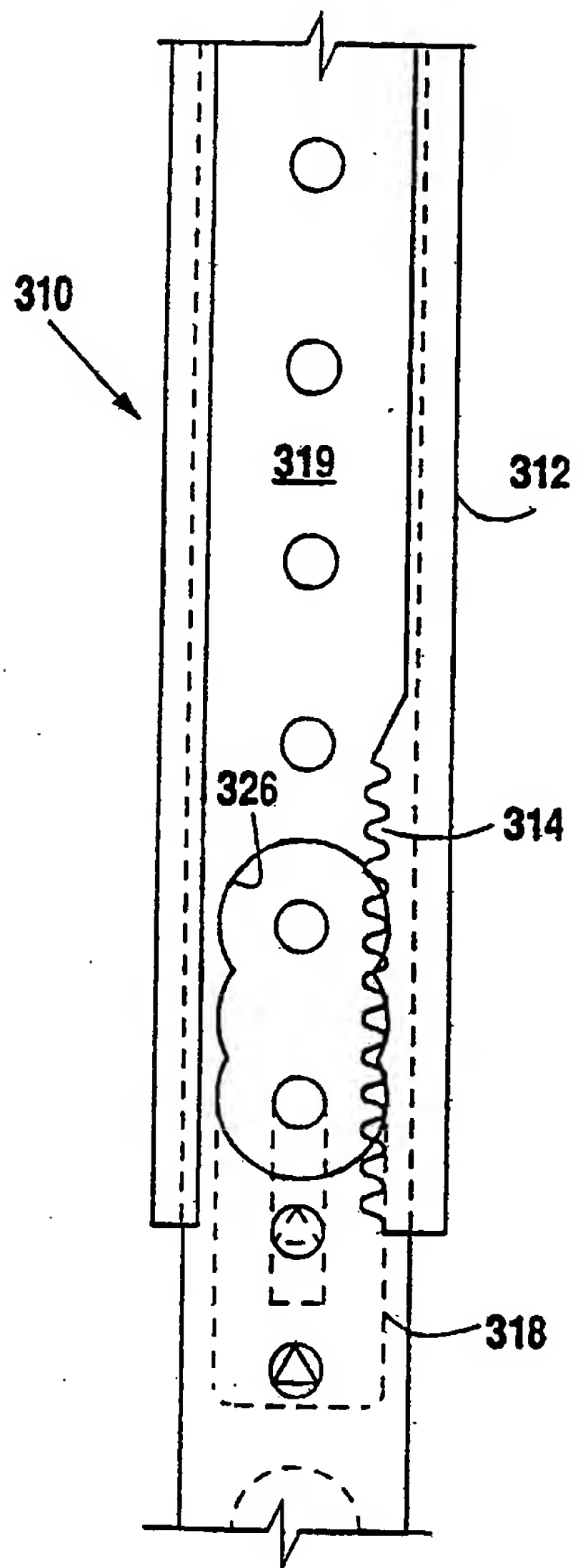


Fig. 18

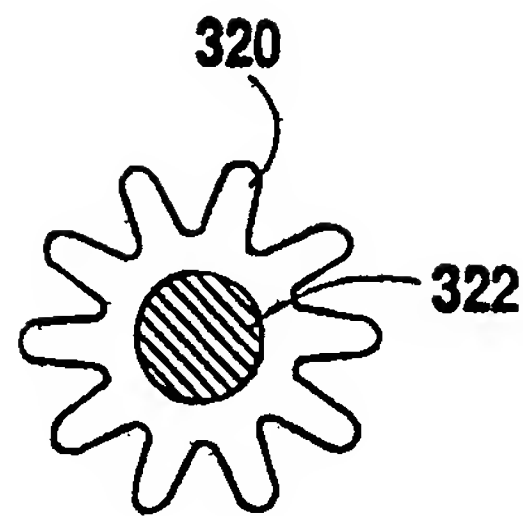


Fig. 22

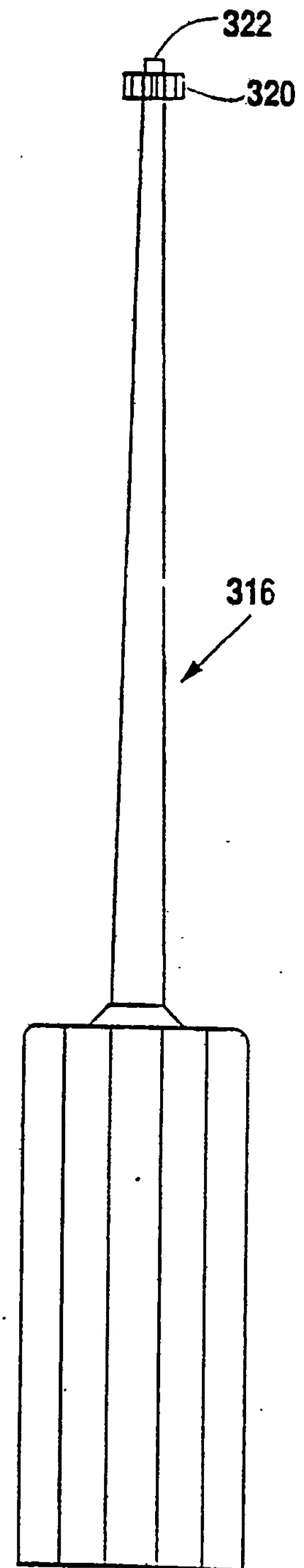


Fig. 21

9 / 12

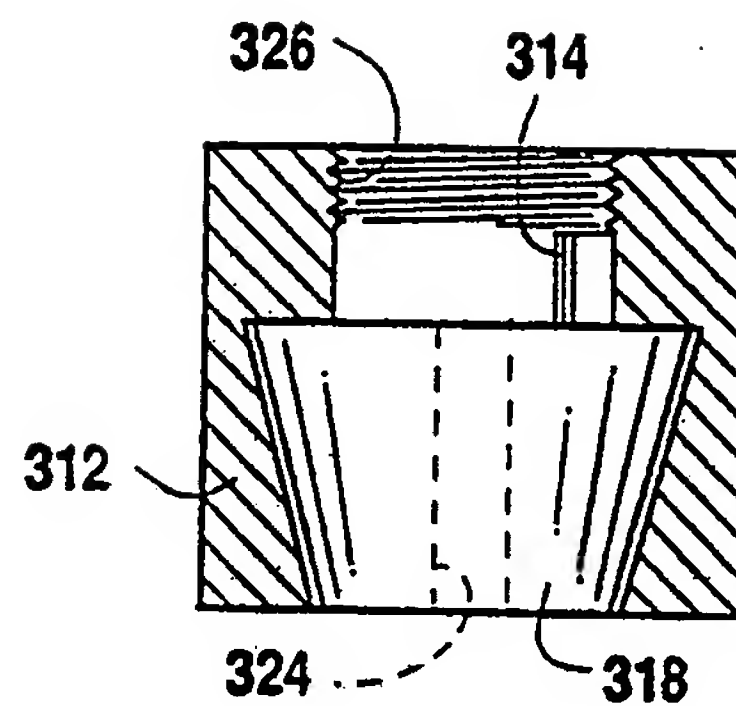


Fig. 23

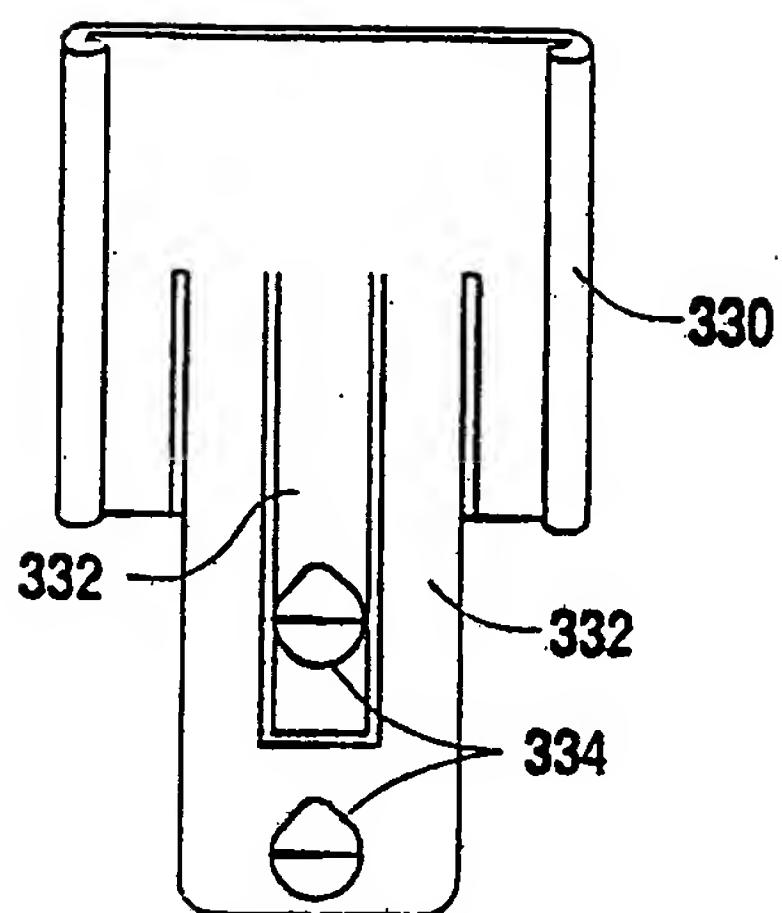


Fig. 25

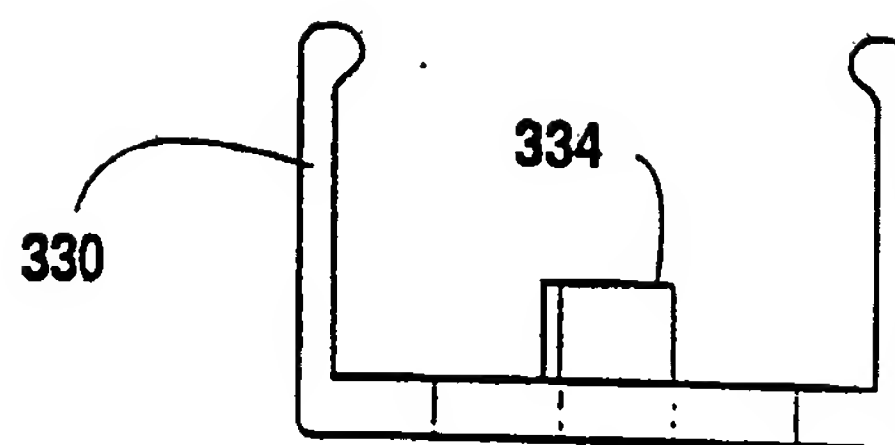


Fig. 26

MICRO-ACCESS DISTRACTION MECHANISM
FOR VERTICAL EXPANDABLE TITANIUM RIB PROSTHESIS

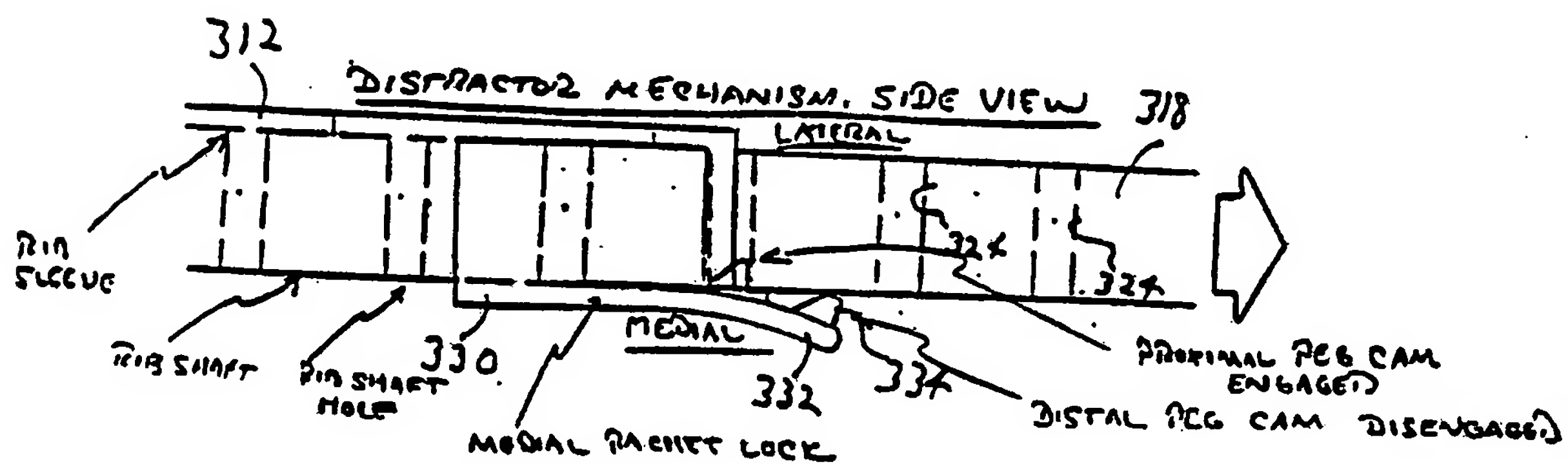


Fig 24

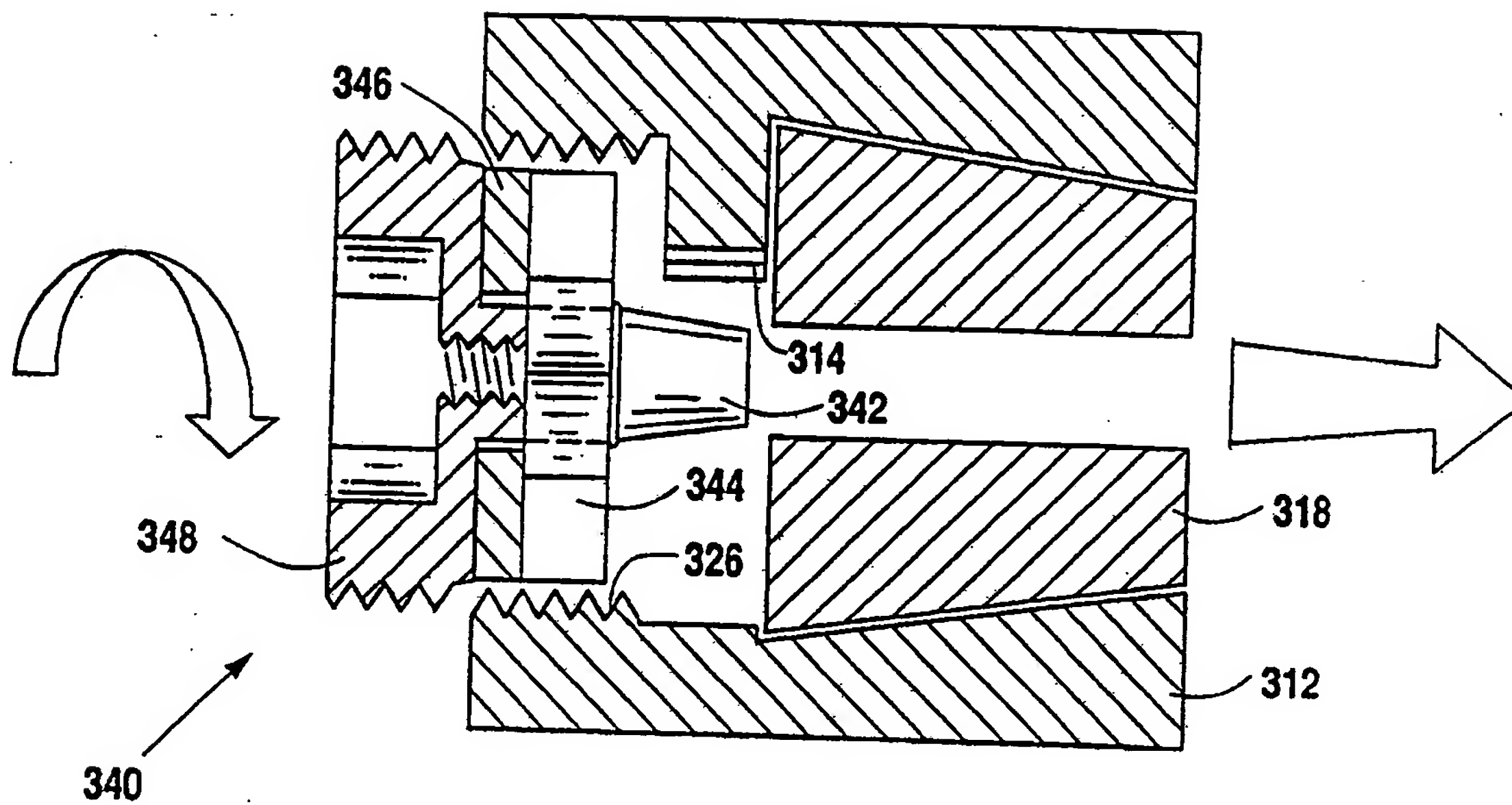


Fig. 27

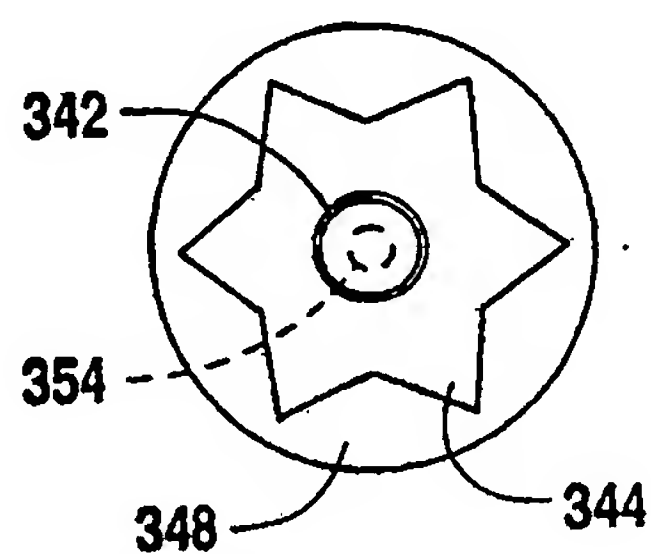


Fig. 29

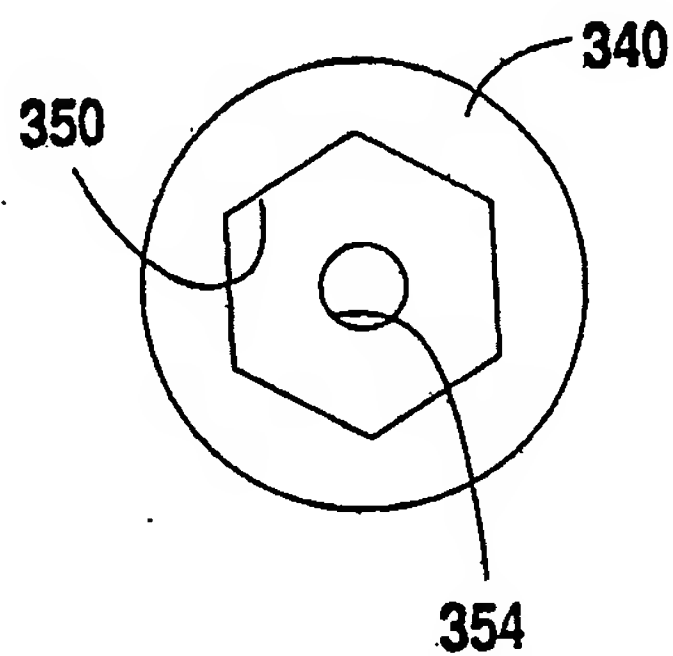


Fig. 30

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US93/04720

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) : A61F 2/28; A61B 17/56

US CL : 606/61; 623/16; 17

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/61, 60, 63, 74, 69-71; 623/16, 17; 602/19

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS: (?costa? or rib?) and scoliq?

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 5,092,889 (Campbell) 03 March 1992, note all the figures.	1-7, 9-13, 15-19 ----- 8, 14, 20
X --- Y	US, A, 4,327,715 (Corvisier) 04 May 1982, note straight bars 1 and bent bars 2 being affixed by means of clips 6 and members 8 in the figures.	1-5, 16-17, 20 ----- 18-19
Y	US, A, 3,242,922 (Thomas) 29 March 1966, see column 1, lines 21-26 and the figures.	8, 14, 20

☒ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:		
"A" document defining the general state of the art which is not considered to be part of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	
"E" earlier document published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed	"&" document member of the same patent family	

Date of the actual completion of the international search

11 August 1993

Date of mailing of the international search report

12 OCT 1993

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Authorized officer

David H. Willse

Facsimile No. NOT APPLICABLE

Telephone No. (703) 308-2903

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/04720

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X — Y	US, A, 4,289,123 (Dunn) 15 September 1981, note that column 3, lines 61-63 imply a complex curve.	1-2, 6, 10, and 16 ----- 8, 18-20
X — Y	US, A, 4,187,841 (Knutson) 12 February 1980, note particularly column 6, lines 42-49.	1-2, 6, 7, 9-12, 16 ----- 8, 18-20
A	US, A, 4,047,523 (Hall) 13 September 1977, note the geometry of the sacral anchor.	8 and 20
A	US, A, 4,263,904 (Judet) 28 April 1981, note the figures.	18-19.

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.